United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510–6175

January 7, 2014

Thomas A. Burke, PhD, MPH
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Dear Dr. Burke:

Thank you for appearing before the Committee on Environment and Public Works on December 17, 2013, at the hearing entitled, "Hearing on the Nominations of Rhea Sun Suh to be Assistant Secretary for Fish and Wildlife and Parks of the U.S. Department of the Interior, Victoria Baecher Wassmer to be Chief Financial Officer of the U.S. Environmental Protection Agency (EPA), Roy K.J. Williams to be Assistant Secretary of Commerce for Economic Development of the U.S. Department of Commerce, and Thomas A. Burke to be Assistant Administrator for Research and Development of the EPA." We appreciate your testimony and we know that your input will prove valuable as we continue our work on this important topic.

Enclosed are questions for you that have been submitted by Senators Boxer, Vitter, and Inhofe for the hearing record. Please submit your answers to these questions by COB January 17, 2014, to the attention of Mara Stark-Alcalá, Senate Committee on Environment and Public Works, 410 Dirksen Senate Office Building, Washington, DC 20510. In addition, please provide the Committee with a copy of your answers via electronic mail to Mara_Stark-Alcala@epw.senate.gov. To facilitate the publication of the record, please reproduce the questions with your responses.

Again, thank you for your assistance. Please contact David Napoliello of the Majority Staff at (202) 224-8832, or Bryan Zumwalt of the Minority Staff at (202) 224-6176 with any questions you may have. We look forward to reviewing your answers.

Sincerely,

Barbara Boxer
Chairman

David Vitter
Ranking Member

Environment and Public Works Committee Nominations Hearing
December 17, 2013
Follow-Up Questions for Written Submission

Questions for Burke

Questions from:

Senator Barbara Boxer

1. Dr. Burke, do you agree that the Environmental Protection Agency (EPA) should use the current, best available science when making decisions on how to best protect human health and the environment, including implementing the recommendations of the National Academy of Sciences (NAS)?

2. Dr. Burke, can you describe how your experiences on numerous NAS Committees and EPA science advisory councils, including the EPA Science Advisory Board, have prepared you to lead scientific research and development at EPA?

Senator David Vitter

1. During the December 17, 2013, nominations hearing you committed to making data and information that underlies scientific studies used to justify EPA rulemakings available to the public. However, when it comes to most regulations under the Clean Air Act, the EPA has a practice of withholding underlying data, making it impossible for Congress and the public to fully understand the scientific underpinnings of major federal regulations. How will you reconcile EPA's current practice of withholding underlying data? How will you ensure that EPA's scientific work is objective and reproducible?

2. Do you believe it is a conflict of interest for a researcher to receive funding from the EPA to conduct research, and then sit on exclusive panels for the agency making decisions based on the very same research?

3. Isn't it correct that you and at least one of your close colleagues, Dr. Jonathan Samet, have received millions of dollars in research grants from the agency? If so,how many EPA research grants have you received? Please describe the scope of the research, which person and office at EPA authorized the grant, and the amount of the grant.

4. EPA research grants are supposed to be awarded in an unbiased and merit-based fashion. However, concerned have been raised that EPA summarily awards the same applicants the limited number of grants. Moreover, Dr. Burke, along with several of his colleagues at the Johns Hopkins University have received numerous EPA research grants. To ensure a competitive and neutral grant process, will you commit to acting without bias or favoritism in distributing EPA research grants?

5. In recent years, the EPA Inspector General (IG) and the Government Accountability Office (GAO) reported instances where EPA grants have been awarded with no public notice, competition, or accountability. Will you commit to adopting all of the IG and GAO's recommendations regarding EPA's grant programs?

6. Francesca Grifo, former senior scientist and director at the Union of Concerned Scientists was recently appointed to serve as EPA's Scientific Integrity Officer within the Office of Research and Development. If confirmed, how do you intend to work with the Scientific Integrity Officer?

7. Are you familiar with Francesca Grifo, EPA's recently appointed Scientific Integrity Officer? Do you believe there is any reason to be concerned that Dr. Grifo's work at the Union of Concerned Scientists may affect her ability to carry out the responsibilities of the Scientific Integrity Officer?

8. In promulgating National Ambient Air Quality Standards (NAAQS), EPA has repeatedly relied on studies that are based on individual cohort data collected in the early 1980s. In 2004, NAS cautioned against relying solely on these studies because of the potential problems given that "cohorts were established decades ago, and some critical data items, including residence history, smoking rates, dietary factors, and other potential confounding and modifying factors, have not been updated." Do you agree with the NAS's caution against using studies that rely so heavily on outdated cohorts? Will you commit to reviewing this issue and reporting back to the Committee with specific guidance on how you intend to use such studies in setting standards and assessing risk?

9. In the Office of Management and Budget's 2013 report on benefits and costs of federal regulations, over 80 percent of the claimed monetized benefits of all federal regulations were based on PM2.5 reductions. However, the report listed six major uncertainties, including a core uncertainty that PM2.5 may not cause the increased risk of mortality at lower concentrations.

    a. Do you agree that these uncertainties are significant within the context of cost-benefit analysis?

    b. Do you believe that EPA should address these uncertainties by developing integrated quantitative uncertainty analyses?

    c. Will you commit to conducting this type of uncertainty analysis in the upcoming ozone NAAQS review?

10. OMB Circular A-4 requires key uncertainties to be disclosed and quantified to the extent possible to inform decision makers and the public about the effects and uncertainties of alternative regulatory actions. However, EPA has a practice of excluding and failing to quantify key uncertainties in the cost-benefit analysis of rulemakings. Will you commit to following all OMB circulars and guidelines? How will you ensure that key uncertainties are included and quantified in the cost-benefit analysis of EPA rulemakings?

11. In FY2013, ORD received approximately $725 million in new appropriations and had $150 in unobligated balances. Yet, no one knows exactly how these funds are used or whether they are being used most efficiently to produce beneficial gains. In effect, EPA has no way of evaluating the environmental "bang for the buck" for each ORD research program. Will you commit to providing Congress an accounting on the costs and potential and actual beneficial gains of each ORD research program? If confirmed, how will you allocate spending in the Office of Research and Development?

12. The psychologist Brian Nosek and colleagues recently wrote: "Publishing norms emphasize novel, positive results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that elicit positive results and ignore negative results." Therefore, it seems that there is less of an emphasis on replication of findings to ensure scientific integrity than developing novel findings.

    a. Do you believe that there is publication bias that leads to greater publication rates of studies reporting positive results compared to studies showing no relationship?

    b. Considering the likelihood of a possible publication bias by journals and a possible bias toward funding positive results by federal agencies, how do you recommend EPA consider this bias in weighing positive and negative studies?

13. The scientific integrity of EPA's hallmark IRIS program has been questioned by Congress as well as the National Academy of Sciences (NAS). While Dr. Ken Olden is working to bring new leadership to the program, there is much more work that needs to be done.

    a. Can you commit to ensuring that all draft and final assessments released by the IRIS program are consistent with the recommendations of the NAS Formaldehyde committee which recommended changes for all IRIS assessments, not just formaldehyde?

b. Science has advanced significantly over the last 25 years. Will you ensure that as part of the improvements in the IRIS program, the Agency will move away from outdated default assumptions and instead always start with an evaluation of the data and use modern knowledge of mode of action -- how chemicals cause toxicity – instead of defaults?

c. Do you agree that standard protocols should be developed to enable all studies to be independently judged based on their quality, strength, and relevance regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

d. To further improve the IRIS Program, can you commit to revising the way hazard values are presented to the public to ensure that critical science policy choices are transparently presented and not comingled with scientific assumptions?

14. While health protection is often seen as the responsibility of EPA risk managers, when it comes to scientific assessments, the job of a risk assessor or toxicologist should be to produce assessments that are predictive of risks.

    a. Do you agree that the role of the IRIS program is to identify values that are predictive of the potential health risks rather than those that provide the most conservative (lowest) value?

    b. Will you support an approach to chemical assessment that results in hazard values that are predictive of actual health risk?

15. It is my understanding that internally the IRIS program no longer relies on definitions that are still publicly used (for example, the definition of the RfD and the meaning of confidence values in IRIS), yet EPA has never used any formal stakeholder or public or peer review process to implement these changes. Instead EPA seems to be relying on a 2002 review received from EPA's Risk Assessment Forum Technical Panel, and staff appear to pick and choose which suggestions they will follow and which they will not implement.

    a. Will you commit to engaging stakeholders before changes to critical definitions and methodologies in the NAAQS and IRIS program are made?

16. Currently, when developing hazard values for exogenous exposures the IRIS Program does not consider natural environmental levels of chemicals, e.g., exposure to minerals from geologic formation, exposure to off-gassing from foliage, or levels naturally produced by the human body as part of its metabolic processes.

    a. Do you agree that chemicals associated with the body's natural metabolic processes should be addressed specifically and separately in the development of a hazard value?

    b. What is your position about addressing natural environmental chemical levels as distinct from background man-made emission?

    c. Do you agree that IRIS hazard values should be able to pass a reality check and accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels?

17. There is a pressing need for priority setting when it comes to chemical evaluations within ORD and throughout EPA.

a. Can you commit to developing a clearly articulated prioritization process for high priority IRIS assessments that benefits from, and is responsive to, engagement from all stakeholders? Will you ensure coordination with other EPA program offices?

18. A 2011 GAO report recommended that EPA needed a more coordinated approach to managing its laboratories. In 2013 a National Academies (NAS) panel began reviewing EPA's laboratory capabilities. If the NAS study and EPA's own review substantiates that unnecessary and costly redundancy do indeed exist, do you commit to expeditiously undertake appropriate actions to consolidate or close labs, and reduce redundant staff?

    a. Can you commit to developing a plan to undertake research in order to build the datasets necessary to establish scientific confidence for regulatory use of a tiered, risk-based approach for using high-throughput/high-content screening assays for safety evaluations (looking to approaches already developed such as the from the Hamner Institute)?

19. Industry and federal research efforts have invested millions to better understand how chemicals interact with biological systems at human exposure levels in order to ensure development of human health risk assessment prediction models that are as accurate and science-based as possible. However, IRIS has a long track record of dismissing these types of scientific biologically-based models and asserting that such approaches cannot prove the defaults are not warranted. Demanding that science proves a negative is an anti-scientific policy and indicates a deep seated prejudice against use of mode of action knowledge to replace defaults.

    a. Why shouldn't EPA use the most up to date knowledge on mode of action and dose response at environmentally relevant exposures in lieu of outdated default approaches for hazard identification and dose response throughout the Agency, including in the IRIS Program?

    b. Many scientists have criticized IRIS for its current framework and suggested using a weight of evidence framework. Thus, a litmus test for an improved IRIS will be adoption and use of a weight of evidence framework that incorporates all of the relevant and reliable data and knowledge of hypothesized modes of action, so that there is a clear and objective presentation of the extent to which existing data and knowledge do, or do not, support each hypothesis, including the default. Assuming you support such an approach, can you provide us with a timeline for when we might see such an approach adopted within IRIS?

20. In developing chemical assessments, such as those in IRIS, there is a blending of science, policy and science policy assumptions and choices throughout the evaluations.

    a. Do you agree that IRIS assessments should explicitly acknowledge and transparently convey the science and assumptions around the science (i.e., handling uncertainty) inherent in IRIS assessments?

21. In the 2009 NAS committee you chaired issued a report recommending there should be one unified approach for dose- response modeling. Unfortunately, such an approach may not always consider the millions of dollars of research that have been invested to explore the mechanisms of action of individual chemicals. Significant activities, coordinated by the Alliance for Risk Assessment, have been undertaken since 2009 to broaden the understanding of dose-response and to link different approaches to conducting dose response to problem formulation. This has resulting in more than 30 published case studies, illustrating qualitative categorization, quantitative screening and in-depth assessments.

a. Do you support linking dose response to problem formulation such that the complexity of the dose response approach is "fit for purpose" and reflects the range of decision options and likely regulatory impacts?

b. Do you believe that any approach implemented needs to put chemical specific information and test data ahead of standardize approaches?

c. Will you support an approach the puts chemical specific information and test data ahead of standardized approaches in the IRIS program?

22. In the past you have suggested, in an NAS report you chaired, that information on nonchemical stressors should be incorporated into assessments and EPA should put further research dollars into evaluating the interactions between chemical and nonchemical stressors.

    a. Considering the struggles ORD is having simply evaluating chemical stressors in the IRIS program, do you believe that ORD has the staff, with requisite qualifications and financial capacity, to also take on evaluations of nonchemical stressors?

    b. Shouldn't ORD first convince Congress, NAS, and all other stakeholders that they can appropriately evaluate chemical stressors before broadening their scope?

23. As noted in "Science and Decisions: Advancing Risk Assessment" (NRC, 2009) "... formal consideration of numerous simultaneous chemical, physical, and psychosocial exposures with evaluation of background disease processes and other dimensions of vulnerability could quickly become analytically intractable if the standard risk-assessment paradigm is followed, both because of the computational burden and because of the likelihood that important exposure and dose-response data will be missing. That points toward the need for simplification of risk-assessment tools in the spirit of iterative risk assessment..."

    a. Since the NAS 2009 report there have been significant advances in the development and application of tiered, iterative tools for cumulative risk assessment, including development by the World Health Organization of a formal framework for risk assessment of combined exposure to multiple chemicals. Do you support use of this WHO framework? If not, why not?

24. Currently the staff in the IRIS Program are the sole arbiters of determining whether and to what extent draft IRIS assessments should be revised to reflect input from peer reviewers and the public. EPA's own Scientific Advisory Board has recommended the use of a "monitor" or "editor."

    a. Can you commit to ensuring that a 3rd party, independent of the IRIS Program, is tasked with ensuring that EPA staff have sufficiently considered and responded to peer reviewer and public input before assessments and other documents are finalized?

25. In previous comments on IRIS reform, you said that EPA's IRIS program is in "crisis" and is in need of reform while further stating "the sleeping giant is that EPA science is on the rocks ... if you fail, you become irrelevant, and that is kind of a crisis." Further, you admonished, "You can't fail this time."

In response to a question you said, "We owe it to the American public, we owe it to the scientific community. . . to have risk assessments based in sound science. It would be better to do it right than destroy the credibility of the process."

The NAS report on formaldehyde was critical of the process as well as the underlying science that EPA used in its draft assessment. Your October 2011 testimony emphasized not only the importance of the process but, more importantly, the scientific conclusions or scientific content of the IRIS assessments.

a. Given the significance of this risk assessment to the scientific process and for restoring the public confidence in EPA's science, it is imperative that you commit to having the NAS relook at the next iteration of the formaldehyde IRIS assessment. Can I have your assurance that this peer review will take place?

26. EPA, at the urging of stakeholders, will convene a scientific workshop on formaldehyde in the first half of 2014. Three key issues have been identified for discussion. I am concerned that this workshop will be similar to typical EPA science workshops of the past where the agency solicits input from a variety of stakeholders, irrespective of their qualifications, listens politely and without comment and provides no resolution or feedback. Quite frankly, that is a waste of time and resources. I want to see difference in interpretation of the data, particularly from the epidemiological studies, narrowed. It is my hope that a robust dialog will help accomplish that. EPA staff should be engaged participants in the dialog, not mute listeners and I suggest EPA engage a professional facilitator and have the proceedings of the workshop published. Will you commit to be personally involved in the development and conduct of this workshop and ensure that the right scientists with the relevant subject matter expertise are at the table?

27. The EPA workshop is timely, important at both the scientific and policy levels, and deals with scientific challenges of the highest order. How will you assure EPA integrates high quality information to help inform regulatory decisions for formaldehyde that presents complex challenges? How will EPA conduct a thorough, state-of-the-art WOE evaluation of the entire database?

28. If you are confirmed, what commitment will you make to ensure EPA's scientific content and scientific conclusions are sound in light of the series of significant scientific shortcomings that the NAS Formaldehyde report identifies and the subsequent recommendations put forward?

29. As you know, Congress directed EPA to contract with the NAS to review the cancer and non-cancer IRIS assessments of inorganic arsenic. It is our understanding that a senior scientist in the IRIS program stated publically in a meeting that any recommendations from the NAS would be unlikely to change the agency's views on the arsenic IRIS assessment. If confirmed, are you prepared to effect organizational and staffing changes to ensure that scientific integrity characterized by objectivity, transparency and scientific rigor is restored?

30. What are your views on how best to use systematic review as a tool to identify and review the body of scientific literature pertinent to a risk assessment of a chemical or substance? It is our understanding that the systematic review method developed by Dr. Birnbaum at the NTP and planned to be used by EPA IRIS automatically codes studies in the literature funded by industry as biased. That would mean that industry studies would not be given the same weight as other studies possibly funded by other organizations. How do you view this practice? How can you justify automatically ascribing bias to studies from or funded by industry, ignoring their scientific merit? Couldn't this distort the science by leaving out reliable and sound scientific studies?

a. Others have pointed to different sources of bias, such as publication bias, which creates incentives, including increased likelihood of funding, toward studies that report positive associations; what are your views on this and similar concerns and how do you plan to take these kinds of bias into account?

31. The recent NAS interim report on inorganic arsenic states, "EPA proposes to use linear low-dose extrapolation as the default for cancer and non-cancer effects." This is in contrast with the EPA cancer guidelines, which supports the use of mode-of-action to determine the shape of the dose-effect relationship. It is also in contrast with general mechanistic understanding of non-cancer dose-response relationships. What are your views on linear versus non-linear approaches to risk assessment? Do you think EPA should pursue the establishment of a threshold at low exposures if the data support such association?

32. As an epidemiologist, please describe how you think the body of epidemiology on a specific substance should be reviewed. For instance, many observers, including the NAS, have criticized EPA for giving too much weight to epidemiological studies of large populations exposed to inorganic arsenic, such as the Taiwan data, just because of the large number of subjects, while giving little credence to studies from the US that observe smaller populations, although the lifestyles, including nutrition, of the large populations are totally different from US lifestyle. Meta-analysis studies have been conducted of US populations that address the smaller number of study subjects, but EPA has ignored those studies. These meta-analyses provide evidence that the dose-response relationship used by NRC 2001 from Taiwan is not consistent with findings from the US, and is higher than what would be derived from studies of US populations. What is your view on the use of meta-analyses as a way to integrate information from smaller studies and to provide a reality check on EPA risk calculations?

33. Studies from places like Bangladesh and Taiwan involve populations with very different nutritional statuses than is found in the US. The NAS Interim Report notes the importance of taking account of these differences in applying these study findings to the US (at p.59). How would you extrapolate from those studies to make the data relevant to the US?

34. How do you view the intersection between epidemiology and toxicology? Many critics believe EPA has been overly reliant on epidemiology and deemphasized mechanistic research that provides guidance for dose-response calculations. Some EPA critics suggest that a reluctance to identify modes of action is a deliberate approach by EPA to allow it to use epidemiological data to validate their modeling.

    a. What steps can you take to correct this bias, whether real or perceived?

    b. Science commentators have noted a concern about "normative science," which is defined as "information that is developed, presented or interpreted based on an assumed, usually unstated, preference for a particular policy choice." [Lackey, Robert T. Normative Science. *Terra Magazine*, Oregon State University, Volume 8, Issue 2 (2013).] What steps will you take to ensure that EPA's science assessments on your watch do not include this kind of normative science?

    c. Another type of concern has been identified: "EPA's use of assumptions that it claims are 'public health protective,' which err on the side of overstating risk when data are lacking.... Such inflated risk estimates can lead to overly stringent regulations and can scramble agency

priorities because the degree of precaution differs across chemicals."[1] How do you intend to guard against this problem? What are your views on the use of empirical data as a "reality check" on overly conservative risk assessments, particularly those resulting from modeling or extrapolation of data? How do you view the application of additional safety factors – particularly when they become cumulative – for sensitive subpopulations or policy considerations such as environmental justice?

35. The NAS 2008 Report: Science and Decisions: Advancing Risk Assessment, frequently referred to as the "Silver Book" strongly recommended that EPA should consider the regulatory impacts of its IRIS hazard assessments. Since then, EPA has proposed IRIS assessments, including the cancer assessment for inorganic arsenic, which would drive regulatory standards below naturally occurring background levels in soil and water. EPA national and regional managers were highly critical of the IRIS proposed 17x increase in the cancer slope for inorganic arsenic, saying the science was " detached from reality" and would have "disastrous consequences" for EPA programs including Safe Drinking Water and RCRA.

    The NAS Silver Book urges EPA to perform extensive examination of risk management implications and options in the first phase of human health hazard assessments. It further recommends involving EPA national program managers (Air, Water, CERCLA, RCRA) in this early phase of assessment so that EPA can then use risk assessment to make more informed choices among those options.

    Do you support this particular recommendation from the NAS Silver Book? Do you believe EPA's IRIS assessments must properly consider the "real world" regulatory and risk management implications of its hazard assessments?

36. What is the cost of EPA's Hydraulic Fracturing study on the potential impacts of hydraulic fracturing on drinking water resources thus far? How long has the agency been engaged in the study? What has the agency done in terms of testing?

37. Has the EPA done any testing in real time for sites that are being drilled now? My understanding is that the agency has tested several sites that were drilled years ago, which is a problem because EPA does not have a good baseline of information and there are other factors which could have caused contamination (agriculture, mining, etc.). How does EPA plan on overcoming the lack of good baseline information and ensuring no conclusions are drawn about hydraulic fracturing without first ruling out any other possible sources of contamination?

38. Has the agency has expanded the scope of the study beyond looking at groundwater? What is the full scope of what the agency is now studying? What are all the various pieces that will be included in the study? Were those asked for by Congress? If the study has been expanded, what justification does the agency have for doing so?

39. What has been the extent of EPA's work with DOE and USGS to date on the study?

40. How are you accounting for fracturing technology, as it is changing quickly and beneficially, as part of the study?

41. There has been some controversy over methane leakage from shale development and hydraulic fracturing. But a recent study from the University of Texas that was published in the Proceedings

[1] Gray & Cohen, "Rethink Chemical Risk Assessments," *Nature*, Vol. 489, p. 27 (9/6/12).

of the National Academy of Sciences found that methane leaks from natural gas development were in line with EPA's data, which showed a leakage rate of only about 1.5 percent. There are several other studies, some of which found high leakage rates, but most seem to suggest that leakage is low and manageable. Based on your review of the scientific literature, what's your understanding of methane leakage from natural gas development, and do you see any environmental benefits of increasing natural gas production and use in the United States?

42. Former EPA administrator Lisa Jackson said, 'I'm not aware of any proven case where the fracking process itself has affected water.' Secretary of Energy Ernest Moniz has said 'I still have not seen any evidence of fracking per se contaminating groundwater.' Interior Secretary Sally Jewell said she is 'not aware of documented cases' of hydraulic fracturing contaminating groundwater. I realize the EPA is currently studying this issue, but based on the evidence already available, do you agree with these officials' assessments?"

43. The increase in domestic energy production is due to the application of two proven engineering technologies – hydraulic fracturing and horizontal drilling. Hydraulic fracturing has been used commercially since the 1940s and directional drilling has been around since the 1930s. Development of resources using these technologies is responsible for 2.1 million American jobs and this number is expected to rise to 3.9 million in 2025. Furthermore, tens of thousands of wells are drilled every year using the process, and we have seen over a million wells drilled in the US with no cases of groundwater contamination. Do you agree that hydraulic fracturing is critical to our economy and our national security? Do you agree that it is a proven technology that has been used safely for over half a century and can be used safely?

    a. Are you aware of any cases where hydraulic fracturing has contaminated drinking water?

44. As part of the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water, the conference report stated that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

    a. Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study? Do you believe it is the SAB ad hoc panel's role to peer review all of the study's reports and projects as part of the study?

45. Also included in the conference report is the statement that "The Agency shall consult with other Federal agencies as well as appropriate State and Interstate regulatory agencies in carrying out the study..."

    a. Are you aware of any other federal agencies currently being consulted in the study? Which agencies will you consult with should you be confirmed and head the ORD and lead the study?

46. Recently, EPA Administrator Gina McCarthy was quoted as saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifers."

    a. Do you agree with that statement?

47. This June, ORD announced it would abandon its flawed drinking water investigation in Pavillion, WY and would instead support a further investigation by the State of Wyoming.

    a. Given the flawed science on display by the agency in Pavillion and ORD's withdrawal, will you exclude the agency's work and data prior to June 2013 from the agency's Congressionally-requested study on the relationship between hydraulic fracturing and drinking water? If not, why not?

    b. ORD abandoned its investigation, yet according to agency statements, continues to "stand[] behind its work and data." How can the agency reconcile these directly contradictory actions? How would you explain to the American people that continuing a flawed investigation is not worth taxpayer resources, yet the agency "stands behind" the work and data that it abandoned? If confirmed, will you correct the record and explain to the public that EPA does not stand behind flawed science?

    c. Are you aware of criticisms of EPA's work in Pavillion by other federal agencies? How would you respond to those criticisms?

    d. How are ORD and the EPA regional office in Denver currently supporting the State of Wyoming's investigation?

48. Is there a reason, particularly as it relates to air science impacts (PM, ozone, etc.) that we don't see the agency using nonlinear threshold analysis? There are concerns that EPA's analysis is allowing the agency to count benefits that just don't exist, or otherwise set standards below naturally occurring background levels. We've seen this in chemical assessments as well, such as on dioxin and inorganic arsenic. How do we resolve the distance between theoretical benefits and empirical evidence?

49. One of the most important responsibilities of the EPA Office of Research and Development is the development of health assessments for EPA's IRIS progam. In September 2011, EPA issued its long-awaited "Toxicological Review of Trichloroethylene (CAS No. 79-01-6) in Support of Summary Information on the Integrated Risk Information System (IRIS)."

    The IRIS Assessment contains a reference concentration ("RfC") of 0.0004 ppm (0.4 ppb or 2 µg/m3) and a reference dose ("RfD") of 0.0005 mg/kg/day for trichloroethylene (TCE). These are values that are considered by EPA to be protective for all noncancer critical effects. EPA's derivation of the RfC/RfD for TCE is based, in part, on Johnson *et al.*, Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environmental Health Perspectives 111: 289-92 (March 2003).

    The RfC/RfD is within the range of background concentrations of TCE in urban air. There is a significant ongoing dispute among the EPA regions as to whether and how this RfC/RfD derived from Johnson *et al.* should be the basis for a short-term TCE exposure limit at Superfund sites. Thus, the proper interpretation and use of this non-GLP study in risk assessment is a question of the highest priority to EPA's Superfund program.

    As noted in the peer review of a recent EPA "TSCA Chemicals Work Plan" assessment of TCE which was highly critical of EPA's reliance on Johnson *et al.*, "[o]ne of the fundamental tenants in science is the reliability and reproducibility of results of scientific investigations."

    The peer reviewers noted:

- At least two GLP-compliant studies conducted under both EPA and OECD guidelines have been unable to reproduce the effect seen by Johnson *et al.*, despite the participation in one of the studies by Johnson herself.

- The dose-response relationship reported in Johnson *et al.* for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.

- The congenital heart defect incidence in control animals in Johnson *et al.* was 86 times the historical control incidence in Charles River rats.

- As California EPA noted in declining to rely upon Johnson *et al.*: "These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits. The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al., 2004)."

Is EPA concerned that the TCE IRIS Assessment appears to rely on an irreproducible study result? Is there any effort underway to correct this Assessment? Does this information presented seem to indicate that the EPA's IRIS program is no longer "crisis" and is being based on the best available science?

50. The Chemical Safety Improvement Act, which is bipartisan legislation drafted by myself and the late Senator Frank Lautenberg, calls for prioritization screening to identify high priority substances for the Agency to focus on. Is this type of priority setting part of problem formulation? And do you support EPA conducting priority setting? How should ORD programs like IRIS prioritize assessments?

    a. Once problem formulation has been completed, in conducting an assessment, do you believe EPA should use an objective evidence-based review system to evaluate studies?

    b. In integrating results across studies and lines of scientific evidence, should EPA use a systematic and transparent approach for assessing the overall weight of the evidence for observed biological or other effects, mechanistic information, and exposure? Will you commit to ensuring that EPA's scientific work product reflects such an approach?

    c. When developing new methods and procedures for conducting assessments, should EPA develop guidance and solicit stakeholder comments and conduct independent scientific peer review? Should peer review ever preclude the involvement of an individual solely based on a current or former affiliation with industry despite any actual showings of bias or conflict (i.e. does industry experience inherently prove bias in your opinion)?

    d. When assessing potential risk, should EPA use an integrated and tiered testing and assessment strategy in which animal testing is minimized by first using all available and relevant data, including information on structure activity relationships, chemical categories and exposure as part of an initial evaluation tier? With a subsequent second tier of additional animal tests and more detailed evaluation undertaken only when warranted?

Senator James Inhofe

1. Dr. Burke, as head of the EPA's R&D Office, you are going to have responsibility for the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water. The conference report mandating the study state that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

   Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study?

2. Dr. Burke, a few weeks ago the EPA Administrator was quoted saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifers."

   Do you agree with this statement?

3. Dr. Burke, you have served as a member of EPA's Science Advisory Board. The SAB serves an important function especially in regard to providing advice on EPA's study on hydraulic fracturing and drinking water.

   a. In your capacity on the SAB, did you have an opportunity to review EPA's study plan?

   b. Do you agree that all of the individual components of the study should be deemed highly influential scientific assessments?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 17 2014

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable David Vitter
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Senator Vitter:

Thank you for the opportunity to respond to the Questions for the Record following the December 17, 2013, hearing entitled, "Hearing on the Nominations of Rhea Sun Suh to be Assistant Secretary for Fish and Wildlife and Parks of the U.S. Department of Interior, Victoria Baecher Wassmer to be Chief Financial Officer of the U.S. Environmental Protection Agency (EPA), Roy K.J. Williams to be Assistant Secretary of Commerce for Economic Development of the U.S. Department of Commerce, and Dr. Thomas A. Burke to be Assistant Administrator for the Office of Research and Development of the EPA." The responses to the questions for Thomas Burke and Victoria Wassmer are enclosed. I hope that this information is helpful to you and the members of the Committee.

If you have any further questions, please contact me or your staff may contact Carolyn Levine in my office at levine.carolyn@epa.gov or (202) 564-1859.

Sincerely,

Laura Vaught

Laura Vaught
Associate Administrator

Enclosures

Questions for the Record
December 17, 2013 Hearing on the Nomination of
Victoria Baecher Wassmer
to be Chief Financial Officer of the
U.S. Environmental Protection Agency
Committee on Environment and Public Works
United States Senate

Senator Boxer

1. **Ms. Wassmer, can you describe how your background and experiences at the FAA and earlier at OMB have prepared you to be the Chief Financial Officer at EPA?**

   Response: I would bring to the role of Chief Financial Officer (CFO) of the Environmental Protection Agency (EPA) 20 years of proven professional experience in progressively high-profile positions, including 15 years of hands-on, practical financial management and leadership within the Federal government. My service to the Federal Aviation Administration (FAA), the Millennium Challenge Corporation, and Office of Management and Budget (OMB) has prepared me for this complex, invigorating opportunity by allowing me to learn firsthand the critical importance and practice of being a responsible, vigilant steward of the American taxpayers' dollars.

   Specifically, in regards to my experience at OMB and FAA, after completing graduate studies in public policy at the Kennedy School of Government, I spent six years at OMB. I gained experience as a policy analyst in the Office of Information and Regulatory Affairs before becoming a program examiner in the Transportation Branch. In these roles, I was responsible for overseeing management, regulatory, policy and budgetary issues over an array of agencies. I later joined the FAA as a manager and then Deputy Director in the Office of Budget. I went on to become a member of the Senior Executive Service and was named the Deputy CFO, responsible for managing the $16 billion annual budget that allows the FAA to achieve its mission of providing the safest, most efficient aerospace system in the world.

   In August 2011, I returned to the FAA as the Assistant Administrator for the Office of Finance and Management. Since then, I have overseen the transition of the agency's finance, acquisition, information technology, and region and center operations services into a single, integrated shared services model. I have also spearheaded agency reforms that ensure resources are properly managed and better optimized to drive cost reductions and financial accountability. Through our centralized approach for common financial services, my team and I have identified value-added financial strategies and performance measures that have realized cost savings, increased efficiency, and reduced duplication in order to better support our customers and the FAA mission. Our data-driven strategies helped the FAA identify approximately $637 million in FY 2013 budget reductions alone, of which approximately $320 million were through contract spending, travel, and other non-pay reductions. During my tenure, we also led the agency in achieving the Certificate of Excellence in

Accountability Reporting (CEAR) Award for the FAA's FYs 2011 and 2012 Performance and Accountability Report (PAR), marking the eighth and ninth time the agency has received this distinguished award. In addition, we led the FAA in receiving unqualified financial statements audit opinions from the agency's independent public accountants in FY2011, 2012 and 2013.

Combined with my formal education and leadership training, my practical experience has prepared me well to be the CFO at EPA.

2. **Ms. Wassmer, can you describe how, with your background and experiences working for the FAA, OMB, and with the Office of the Vice President's Millennium Challenge, you will provide a fresh perspective and how you will work to change, as appropriate, EPA's financial management systems?**

Response: If given the honor of serving as the Chief Financial Officer (CFO) of the Environmental Protection Agency (EPA), once I am a member of the EPA team, my first priority will be to use every means possible to identify the changes needed to improve the performance, integrity, and transparency of the EPA's financial management systems. As part of my immersion in the agency, I will meet with a range of internal stakeholders and external customers, review financial documents, and investigate existing practices, policies, and procedures to gain a comprehensive familiarity of the systems that are currently in place and to identify opportunities for improvement. While I cannot provide examples of specific changes I would make until I have an educated, hands-on understanding of the agency's current state, my goal and focus over the course of my appointment will be to make changes in the near-term that will expedite improvements needed to ensure the integrity of the EPA's financial practices while developing and implementing a long-term plan that will drive the continuous improvement of those practices. I will rely heavily on lessons learned and best practices gained over my 20-year career and specifically through my service to the Federal Aviation Administration (FAA), Office of Management and Budget (OMB), and the Millennium Challenge Corporation to apply a strategic, data-driven approach to implementing sound business practices that will ensure performance and accountability.

In my current work as Assistant Administrator for the Office of Finance and Management for the FAA as well as in my previous roles as Vice President of Administration & Finance/CFO for the Millennium Challenge Corporation and the FAA, I have been responsible for providing oversight and management for each agency's complex, multi-billion dollar appropriations and ensuring accountability to the American taxpayer for all laws, policies, and procedures. In each of these positions as well as in my role as Deputy Director of the Office of Budget at FAA, I have also spearheaded the reorganization of financial organizations and operations to optimize financial reporting, financial systems, internal controls, audit and accounting standards, budget formulation and execution, performance management and cost controls.

Regardless of the current health of a financial management system, my experience has taught me that the role of a leader is to ensure that the system remains on a continuous path of improvement. As with any process, something can always be done better. It is a matter of

proactively looking for those opportunities by tracking and analyzing meaningful data, listening to the feedback of stakeholders, and measuring performance against relevant targets. This is what I have done at the FAA, OMB, and the Millennium Challenge Corporation, and it is what I would do as CFO of the EPA.

3. **Ms. Wassmer, one of the roles of the Chief Financial Officer is to oversee EPA's goal setting process. Can you explain how you would ensure that EPA is working every day to enhance safeguards for pregnant women, children, and other vulnerable populations?**

   Response: If confirmed as the Chief Financial Officer (CFO), goal setting would be an important responsibility of mine and integral to Agency decision making. I look forward to working within EPA to set forth strategic direction and consider tough choices needed to meet our mission. As I have done at FAA and in previous positions, I will work with the relevant office(s) at EPA to use a data-driven approach to inform EPA's planning process to ensure that the appropriate level of safeguards are in place for all of the American public, including sensitive populations.

4. **Ms. Wassmer, can you describe what in your background best prepares you to be EPA's Chief Financial Officer?**

   Response: Over my 20+year career since graduate school, I have worked in all levels of the government's financial arena – from a new analyst to a seasoned Assistant Administrator for Finance and Management. I understand and have successfully shouldered the important responsibility, the increased scrutiny, and the critical accountability that comes with being a Chief Financial Officer (CFO) and ensuring the effective, judicious execution of an agency's budget. Yet, as with everyone, I am the sum total of my experiences. Many of those experiences have taught me what works in a particular situation, while others have shown me what does not work. In my professional life, the worker, the employee, the colleague, the leader I am today was formed by each of those experiences, and it is that, more than anything, which has best prepared me to successfully take on the role of the Environmental Protection Agency's CFO.

   Growing up, my parents instilled in me through their own careers and actions the belief that public service is a noble calling and that it is an honor to be in a position where you can serve others. In my first jobs out of college as a job developer for tradeswomen and project manager in Chicago, I learned how you can help others excel by ensuring they have the opportunity to be successful. Through my work in South Africa, I learned that if you engage the people who are most affected by a problem, their input will often help you identify the best solution. It also reinforced my belief that given opportunities, individuals can achieve great heights and that everyone deserves to be treated with dignity and respect. During my time at OMB, I learned from master senior executives and policy officials who showed me each day through their actions that integrity is always a personal option and that you should always strive to do the right thing, even when it is the harder or unpopular path. At the Millennium Challenge Corporation, I learned the true value of a dollar, and how far you can stretch it if you optimize your resources and focus on what is truly needed, not what is most wanted. I was reminded that a fresh perspective can help you identify new ways to work

smarter and achieve cost savings that can be reinvested in the programs that make the biggest difference.

As the Assistant Administrator for the Office of Finance and Management, I stood-up a new, first-of-its-kind shared services organization that today provides efficient and effective enterprise-wide business solutions and services to customers across the FAA as well as to the Department of Transportation and other government agencies. This has been an incredible learning experience. It taught me how to work with many diverse senior executives with differing opinions and personal agendas and how to facilitate consensus for the adoption of the best possible decisions for the agency. It also reinforced my belief that as the leader of an organization, you are ultimately responsible for the decisions made and the quality of the services provided. So, you have to set the bar high, make your expectations clear, continually take the pulse of your organization, proactively identify and try to fix what does not work or what could be improved, put reliable systems in place that measure performance, be open to a course correction, and help make the people you work with and the people you work for successful.

While I could not begin to list everything I have learned and been taught over the course of my career, I have a deep understanding of what it takes to be a leader in a government agency and to be a responsible steward of the taxpayers' resources. I will bring these experiences with me if I am given the opportunity to serve as the CFO of the EPA, and I will work every day to restore and ensure the integrity of the agency's financial management systems and to earn the trust of you and the American taxpayers.

5. **Ms. Wassmer, one of the EPA Chief Financial Officer's responsibilities is to be the agency audit follow-up official responsible for agency-wide audit resolution and ensuring action officials implement corrective actions in response to OIG recommendations. Do you agree that, if confirmed, you will work with agency officials to ensure that appropriate actions are taken to implement corrective actions in response to OIG recommendations?**

Response: I respect the Inspector Generals' independent oversight of agency programs and operations. I believe an IG's mission to promote efficiency, effectiveness, and prevent and detect fraud, waste, and abuse aligns with a Chief Financial Officer's ethical and legal responsibility to ensure sound and proper use of the American taxpayers' dollars. If confirmed, I will work with the EPA's OIG and program and regional offices, as appropriate, to agree on and implement appropriate corrective actions as expeditiously as possible.

Senator Vitter

1. **Are you familiar with the criminal case against John C. Beale? As you should know, Beale was a career civil servant that bilked the agency for millions in unearned bonus pay, unauthorized travel, and by simply being paid for work he did not do. As the chief financial officer for the agency, it will in large part be your responsibility to develop and implement new systems to protect against this sort of fraud in the future. Please share with the Committee the steps you will take in your first 100 days to reform the agency and prevent future fraudulent acts.**

   Response: I have only seen press coverage and early warning reports issued by the Inspector General in December that were prepared at your request. Based on what I have seen, strengthened internal controls and careful monitoring of those controls would deter such conduct in the future and, if detected, end it more quickly and effectively. I take very seriously my responsibility to be a trustworthy steward of taxpayers' dollars. If confirmed, I will review the facts of the incident and the actions EPA has completed or plans to complete to ensure that ineffective controls, which may have failed to prevent Mr. Beale's fraud, are addressed swiftly and that compliance is monitored closely.

2. **In the case of John Beale, it appears that he could not have been able to accomplish his fraud against the American taxpayer without the assistance, either knowing or unknowing, or other EPA staff. For example, the Committee has learned that Robert Brenner was often the one who approved Beale's requests for bonuses and that Beth Craig approved his travel. Have you had the opportunity to review the facts of this case? Do you concur with my assessment that others at the agency participated, perhaps unknowingly, in Beale's fraud? What do you plan to do in your position as CFO to ensure that EPA employees are not bilking the taxpayers out of millions?**

   Response: I have not had the opportunity to review the facts of this case in detail. However, if confirmed, I will conduct a thorough and expeditious review of the facts and the actions EPA has completed or plans to complete to ensure the appropriate internal controls and compliance monitoring are in place to prevent the fraud Mr. Beale perpetuated. I also will ensure the OIG receives my full cooperation in its ongoing investigation.

3. **In the case of John Beale-did you know that he was still on pay roll AFTER his manager-Gina McCarthy-believed he had retired from the agency? How can something like that happen? Do you agree with me that such a disconnect is unacceptable?**

   Response: Again, I am not familiar with the details of this case. If confirmed, I will review the facts of the incident and ensure that EPA has taken or takes the necessary actions to prevent future fraud such as this.

4. **Are you aware of the fact that the EPA Inspector General has identified "Workforce Planning" as a serious management and performance challenge for the agency? Are you aware of the fact that according to the EPAIG, EPA currently does not identify**

the essential functions of staff based on data? Do you agree with me that a failure to identify essential agency functions based on data is a serious failing? Wouldn't the Harvard School of Public Policy frown on such a shabby state of affairs?

Response: I can assure you that I value the prudent use of sound, reliable data to inform decisions. In fact, throughout my career, I have relied heavily on data-driven approaches to make strategic business decisions at the corporate level. I am aware of the Inspector General's work on this important issue and understand its concerns regarding workload planning at EPA. If confirmed, I will review the issue and the actions EPA has completed or plans to complete to improve workload planning across the Agency so I can make a more informed decision regarding the appropriate next steps to move the Agency forward on this issue.

5. **Are you aware of the fact that despite prodding from GAO and the IG, EPA has not developed analytical methods or collected data to measure its workload and the corresponding workforce levels necessary to carry out that workload? How do you intend to remedy that?**

   Response: I respect the Inspector Generals' and Government Accountability Office's independent oversight of agency programs and operations. Their work to promote the efficient and effective use of the American taxpayers' dollars aligns with a Chief Financial Officer's duty to be a responsible steward of those resources. I am aware of the OIG and GAO reports and understand their concerns regarding workload planning at EPA. If confirmed as CFO, I will take a close look at this issue so that I can determine the appropriate next steps to drive the Agency's progress on data-driven workforce planning.

6. **Are you aware that when the EPW Committee asked EPA how much money the agency spent to conduct the watershed assessment of the Bristol Bay Watershed in Alaska, EPA admitted to my staff that they had no way of calculating the amount of in house resources dedicated to the effort? Do you find such a state of affairs acceptable? If not, will you commit to me today that as the CFO you will develop a process that will require the agency to know how much taxpayer dollars are being spent on agency activities?**

   Response: I was not aware of this issue until recently, and I am not familiar with the details. However, in my experience, cost accounting can provide useful financial management data to inform decisions to allocate budget resources, initiate or modify programs or projects, improve efficiency, and evaluate performance. If confirmed as CFO, I will review the issue thoroughly and take the appropriate action to expeditiously respond to your concern.

7. **As you may know, there have been 3 OIG reports on EPA justification for workforce level with the first being released on December 20, 2010, the second on September 14, 2011 and the last on August 30, 2013. Over the span of 3 years these reports have come to the conclusion that EPA is not meeting the requirements set by Title 5 CFR Part 250.202 the *Human Capital Assessment and Accountability Framework*, which states that**

workforce planning systems include a workforce analysis process that identifies the size and characteristics of the workforce needed to meet organizational goals. Contrary to this requirement EPA has not conducted the necessary workload analysis to determine the correct number of FTEs needed to specifically carry out the most essential parts of its mission. EPA has not done so for 20 years and still does not do so as of 2013. If confirmed as EPA's next CFO, will you commit to implementing a system can accurately model the workforce needs of the agency.

Response: As I stated previously, I assure you that I value the prudent use of sound, reliable data to inform decisions, and I have relied heavily on data-driven approaches throughout my career to make strategic business decisions at the corporate level. I am aware of the OIG reports and understand its concerns regarding workload planning at EPA. If confirmed as CFO, I will take a close look at the specifics and determine the appropriate next steps to move the Agency forward on this issue.

Questions for the Record
December 17, 2013 Hearing on the Nomination of
Thomas Burke to be Assistant Administrator of the
Office of Research and Development, U.S. Environmental Protection Agency
Committee on Environment and Public Works
United States Senate

Senator Barbara Boxer

1. Dr. Burke, do you agree that the Environmental Protection Agency (EPA) should use the current, best available science when making decisions on how to best protect human health and the environment, including implementing the recommendations of the National Academy of Sciences (NAS)?

Response: I agree that EPA should use the most current and best available peer reviewed science to inform decisions on protecting health and the environment. As chair and member of several National Academy of Sciences studies examining EPA science, I also agree that the agency should be responsive to the recommendations of the Academy and work to implement them to the best degree possible.

2. Dr. Burke, can you describe how your experiences on numerous NAS Committees and EPA science advisory councils, including the EPA Science Advisory Board, have prepared you to lead scientific research and development at EPA?

Response: I have worked closely with the agency as a member of the Science Advisory Board and member of the Board of Scientific Counselors. I have also served on the Board on Environmental Studies and Toxicology of the National Academy of Sciences and chaired a number of major Academy studies of EPA science. This experience has given me a strong understanding of the strengths and challenges of the EPA Office of Research and Development, and has provided me a valuable perspective of the views of a broad range of EPA stakeholders including business and industry, state health and regulatory agencies, academia, and community and environmental advocates.

Senator David Vitter

1. During the December 17, 2013, nominations hearing you committed to making data and information that underlies scientific studies used to justify EPA rulemakings available to the public. However, when it comes to most regulations under the Clean Air Act, the EPA has a practice of withholding underlying data, making it impossible for Congress and the public to fully understand the scientific underpinnings of major federal regulations. How will you reconcile EPA's current practice of withholding underlying data? How will you ensure that EPA's scientific work is objective and reproducible?

Response: Transparency and scientific integrity are very important to the agency's work. I understand that EPA has taken appropriate and substantial steps to increase transparency and public access to information. However, it is essential to protect the privacy of individuals who have served as subjects in studies and their personal health information. If confirmed, I intend to continue the agency's ongoing efforts to ensure that scientific and technical information that is intended to inform or support agency decisions continues to be based on the best available science.

2. Do you believe it is a conflict of interest for a researcher to receive funding from the EPA to conduct research, and then sit on exclusive panels for the agency making decisions based on the very same research?

Response: I believe it is important to have a balanced perspective in any review of research results and findings. Receiving funding from EPA should not disqualify outstanding scientists from participating in scientific panels however it is important to have strong and transparent measures to identify conflicts of interest. In my experience, science advisors may provide recommendations regarding scientific evidence but are not "decision makers" for the agency.

3. Isn't it correct that you and at least one of your close colleagues, Dr. Jonathan Samet, have received millions of dollars in research grants from the agency? If so, how many EPA research grants have you received? Please describe the scope of the research, which person and office at EPA authorized the grant, and the amount of the grant.

Response: Dr. Samet is a former colleague; he left Johns Hopkins in 2008 to take a position at the University of Southern California. Although we worked together on many academic activities, I was not a co-investigator in any of his EPA funded research.

The only major research grant I have received from EPA was a highly competitive Science to Achieve Results (STAR) grant in 2008 from the ORD National Center for Environmental Research entitled "Longitudinal Indicators of Policy Impact on Pollution, Exposure and Health Risk" The amount of the award was $499,961. I received funding from EPA Region 3 through a cooperative agreement in 1994 to address community environmental health concerns in South Philadelphia. The project was entitled "Pilot Multi-Media Environmental Health Characterization of South and Southwest Philadelphia" and the total funding was $519,000.

4. EPA research grants are supposed to be awarded in an unbiased and merit-based fashion. However, concerns have been raised that EPA summarily awards the same applicants the limited number of grants. Moreover, Dr. Burke, along with several of his colleagues at the Johns Hopkins University have received numerous EPA research grants. To ensure a competitive and neutral grant process, will you commit to acting without bias or favoritism in distributing EPA research grants?

Response: If confirmed, I will work to ensure that the research grant process is competitive and that the criteria for scoring the applications are clearly presented and transparent.

5. In recent years, the EPA Inspector General (IG) and the Government Accountability Office (GAO) reported instances where EPA grants have been awarded with no public notice, competition, or accountability. Will you commit to adopting all of the IG and GAO's recommendations regarding EPA's grant programs?

Response: I take seriously the role that the Inspector General and Government Accountability Office play in assessing the accountability of government programs, and if confirmed, I would welcome their recommendations. While I am not familiar with reports referenced in this question, if confirmed, I commit to reviewing the recommendations of the IG and GAO and giving them due consideration.

6. Francesca Grifo, former senior scientist and director at the Union of Concerned Scientists was recently appointed to serve as EPA's Scientific Integrity Officer within the Office of Research and Development. If confirmed, how do you intend to work with the Scientific Integrity Officer?

Response: As I mentioned in my opening statement, I have a deep respect for the work of the agency scientists and I believe science is the "backbone" of EPA decision-making, and has been the foundation of our nation's environmental progress over the past four decades. Science should be credible, transparent, and inclusive. If confirmed, I look forward to working with Dr. Grifo to see that the agency's Scientific Integrity Policy is fully implemented across the Office of Research and Development and EPA as a whole.

7. Are you familiar with Francesca Grifo, EPA's recently appointed Scientific Integrity Officer? Do you believe there is any reason to be concerned that Dr. Grifo's work at the Union of Concerned Scientists may affect her ability to carry out the responsibilities of the Scientific Integrity Officer?

Response: Although I do not know Dr. Grifo personally, I have reviewed her vitae and believe that her training and experience, including her work with the Union of Concerned Scientists, provide her with strong credentials to serve as Scientific Integrity Officer. If confirmed, I look forward to working with her to ensure the integrity of EPA science.

8. In promulgating National Ambient Air Quality Standards (NAAQS), EPA has repeatedly relied on studies that are based on individual cohort data collected in the early 1980s. In 2004, NAS cautioned against relying solely on these studies because of

the potential problems given that "cohorts were established decades ago, and some critical data items, including residence history, smoking rates, dietary factors, and other potential confounding and modifying factors, have not been updated." Do you agree with the NAS's caution against using studies that rely so heavily on outdated cohorts? Will you commit to reviewing this issue and reporting back to the Committee with specific guidance on how you intend to use such studies in setting standards and assessing risk?

Response: EPA's work to protect public health and the environment through programs such as promulgating National Ambient Air Quality Standards needs to be based on strong science. The NAAQS program is very important, and if confirmed, I look forward to reviewing this issue and working to ensure that the Integrated Science Assessments that provide the foundation for NAAQS decisions reflect the best possible science.

9. In the Office of Management and Budget's 2013 report on benefits and costs of federal regulations, over 80 percent of the claimed monetized benefits of all federal regulations were based on PM2.5 reductions. However, the report listed six major uncertainties, including a core uncertainty that PM2.5 may not cause the increased risk of mortality at lower concentrations.

a. Do you agree that these uncertainties are significant within the context of cost-benefit analysis?

b. Do you believe that EPA should address these uncertainties by developing integrated quantitative uncertainty analyses?

c. Will you commit to conducting this type of uncertainty analysis in the upcoming ozone NAAQS review?

Response: EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflect the best possible science.

10. OMB Circular A-4 requires key uncertainties to be disclosed and quantified to the extent possible to inform decision makers and the public about the effects and uncertainties of alternative regulatory actions. However, EPA has a practice of excluding and failing to quantify key uncertainties in the cost-benefit analysis of rulemakings. Will you commit to following all OMB circulars and guidelines? How will you ensure that key uncertainties are included and quantified in the cost-benefit analysis of EPA rulemakings?

Response: While I am not familiar with the specific requirements of that OMB circular and how it relates to the duties of ORD, if confirmed, I would certainly commit to follow all applicable OMB circulars and guidelines and to support the broader agency's efforts to comply with any such requirements. A big part of the ORD mission is to help provide information to fill key data and science gaps which can help to more fully characterize

uncertainty. If confirmed, I will work very hard to provide the agency with the tools and data necessary to deal with uncertainty in our regulatory analyses.

11. In FY2013, ORD received approximately $725 million in new appropriations and had $150 in unobligated balances. Yet, no one knows exactly how these funds are used or whether they are being used most efficiently to produce beneficial gains. In effect, EPA has no way of evaluating the environmental "bang for the buck" for each ORD research program. Will you commit to providing Congress an accounting on the costs and potential and actual beneficial gains of each ORO research program? If confirmed, how will you allocate spending in the Office of Research and Development?

Response: I am not familiar with the details of ORD's budget. If confirmed, I look forward to reviewing this issue to ensure that the resources are being utilized prudently and are focused on the priorities important to supporting the agency's mission.

12. The psychologist Brian Nosek and colleagues recently wrote: "Publishing norms emphasize novel, positive results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that elicit positive results and ignore negative results." Therefore, it seems that there is less of an emphasis on replication of findings to ensure scientific integrity than developing novel findings.

a. Do you believe that there is publication bias that leads to greater publication rates of studies reporting positive results compared to studies showing no relationship?

Response: Yes, I agree that there is a bias toward greater publication of positive studies. There may be many factors that contribute to this, including a lower submission rate by investigators when study results are negative and the possibility that weaknesses in study design may contribute to a higher likelihood of negative results.

b. Considering the likelihood of a possible publication bias by journals and a possible bias toward funding positive results by federal agencies, how do you recommend EPA consider this bias in weighing positive and negative studies?

Response: EPA should consider all relevant well-conducted and peer-reviewed studies, regardless of whether they are positive or negative, and include clear criteria for inclusion and exclusion of studies. Review and assessment of studies should be based upon the quality of the research, including study objectives and design, statistical power, presentation of the findings and conclusions, and consideration of study limitations, uncertainty, bias and confounding.

13. The scientific integrity of EPA's hallmark IRIS program has been questioned by Congress as well as the National Academy of Sciences (NAS). While Dr. Ken Olden is working to bring new leadership to the program, there is much more work that needs to be done.

a. Can you commit to ensuring that all draft and final assessments released by the IRIS program are consistent with the recommendations of the NAS Formaldehyde committee which recommended changes for all IRIS assessments, not just formaldehyde?

Response: My understanding is that the IRIS Program has been implementing the recommendations using a phased approach, consistent with the advice of the National Research Council (NRC), making the most extensive changes to assessments that are in the earlier stages of assessment development. Additionally, in July 2013, EPA announced enhancements to the IRIS Program that will improve the science quality of assessments, improve the productivity of the Program, and increase transparency. These changes are consistent with the NRC recommendations. If confirmed, I look forward to working with the National Center for Environmental Assessment.

b. Science has advanced significantly over the last 25 years. Will you ensure that as part of the improvements in the IRIS program, the Agency will move away from outdated default assumptions and instead always start with an evaluation of the data and use modem knowledge of mode of action -- how chemicals cause toxicity- instead of defaults?

c. Do you agree that standard protocols should be developed to enable all studies to be independently judged based on their quality, strength, and relevance regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

d. To further improve the IRIS Program, can you commit to revising the way hazard values are presented to the public to ensure that critical science policy choices are transparently presented and not comingled with scientific assumptions?

Response: EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflects the best possible science and that information is communicated in a transparent manner.

14. While health protection is often seen as the responsibility of EPA risk managers, when it comes to scientific assessments, the job of a risk assessor or toxicologist should be to produce assessments that are predictive of risks.

a. Do you agree that the role of the IRIS program is to identify values that are predictive of the potential health risks rather than those that provide the most conservative (lowest) value?

b. Will you support an approach to chemical assessment that results in hazard values that are predictive of actual health risk?

Response: IRIS assessments are designed to be scientific reports that provide information on a chemical's hazards and, when supported by available data, quantitative toxicity values for cancer and non-cancer health effects. EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflect the best possible science.

15. It is my understanding that internally the IRIS program no longer relies on definitions that are still publicly used (for example, the definition of the RfD and the meaning of confidence values in IRIS), yet EPA has never used any formal stakeholder or public or peer review process to implement these changes. Instead EPA seems to be relying on a 2002 review received from EPA's Risk Assessment Forum Technical Panel, and staff appear to pick and choose which suggestions they will follow and which they will not implement.

a. Will you commit to engaging stakeholders before changes to critical definitions and methodologies in the NAAQS and IRIS program are made?

Response: Yes, if confirmed, I will review the definition of the RfD and the confidence values.

16. Currently, when developing hazard values for exogenous exposures the IRIS Program does not consider natural environmental levels of chemicals, e.g., exposure to minerals from geologic formation, exposure to off-gassing from foliage, or levels naturally produced by the human body as part of its metabolic processes.

a. Do you agree that chemicals associated with the body's natural metabolic processes should be addressed specifically and separately in the development of a hazard value?

Response: This is an important consideration in understanding and managing incremental risk from environmental exposure. Since there are many natural products of metabolism that may have toxic effects if they are out of balance, the fact that they are naturally produced does not make them "safe" at all doses.

b. What is your position about addressing natural environmental chemical levels as distinct from background man-made emission?

Response: I believe that these are important considerations that should be presented as part of the problem formulation prior to undertaking a risk assessment. However, health based regulatory standards do not distinguish between natural occurring and man-made sources. Addressing incremental risks above background is an important consideration in risk management and the determination of "acceptable" risk in regulatory decision making. Reducing risks below background levels may not always be technically feasible.

c. Do you agree that IRIS hazard values should be able to pass a reality check and accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels?

Response: I cannot agree without more information about the specific pollutant of concern. The adverse effects of hazardous agents are not driven by whether or not they are "naturally" occurring. For example radon is known to increase risk of lung cancer. The source of the exposure does not impact the dose at which an adverse effect is observed. Natural occurrence and background levels are more appropriately considered in the risk management strategy.

17. There is a pressing need for priority setting when it comes to chemical evaluations within ORD and throughout EPA.

a. Can you commit to developing a clearly articulated prioritization process for high priority IRIS assessments that benefits from, and is responsive to, engagement from all stakeholders? Will you ensure coordination with other EPA program offices?

Response: I understand that EPA has previously committed to the Government Accountability Office that it will better describe for internal and external stakeholders and the public the nomination and selection process for chemicals for IRIS toxicity assessments, including the rationale for not selecting nominated chemicals for the full IRIS assessment. If confirmed, I look forward to working with scientists in the National Center for Environmental Assessment on this issue.

18. A 2011 GAO report recommended that EPA needed a more coordinated approach to managing its laboratories. In 2013 a National Academies (NAS) panel began reviewing EPA's laboratory capabilities. If the NAS study and EPA's own review substantiates that unnecessary and costly redundancy do indeed exist, do you commit to expeditiously undertake appropriate actions to consolidate or close labs, and reduce redundant staff?

Response: I understand that EPA has undertaken to do a study of the laboratory enterprise and has engaged the National Academies as part of this process. If confirmed, I will look into the progress of this effort.

a. Can you commit to developing a plan to undertake research in order to build the datasets necessary to establish scientific confidence for regulatory use of a tiered, risk-based approach for using high-throughput/high-content screening assays for safety evaluations (looking to approaches already developed such as the from the Hamner Institute)?

Response: EPA's computational toxicology research program is recognized nationally and internationally as bringing new science to bear on chemical safety and has made great progress in this area since the release of the NAS report.

19. Industry and federal research efforts have invested millions to better understand how chemicals interact with biological systems at human exposure levels in order to ensure development of human health risk assessment prediction models that are as accurate -and science-based as possible. However, IRIS has a long track record of dismissing these types of scientific biologically-based models and asserting that such approaches cannot prove the defaults are not warranted. Demanding that science proves a negative is an anti-scientific policy and indicates a deep seated prejudice against use of mode of action knowledge to replace defaults.

a. Why shouldn't EPA use the most up to date knowledge on mode of action and dose response at environmentally relevant exposures in lieu of outdated default approaches for hazard identification and dose response throughout the Agency, including in the IRIS Program?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that EPA's work reflects the best possible science.

b. Many scientists have criticized IRIS for its current framework and suggested using a weight of evidence framework. Thus, a litmus test for an improved IRIS will be adoption and use of a weight of evidence framework that incorporates all of the relevant and reliable data and knowledge of hypothesized modes of action, so that there is a clear and objective presentation of the extent to which existing data and knowledge do, or do not, support each hypothesis, including the default. Assuming you support such an approach, can you provide us with a timeline for when we might see such an approach adopted within IRIS?

Response: Hazard identification involves integrating evidence from human, animal, and mechanistic studies in order to draw conclusions about the hazards associated with exposure to a chemical. In general, IRIS assessments integrate evidence consistent with a framework developed by Sir Bradford Hill, which outlines aspects — such as consistency, strength, coherence, specificity, dose-response, temporality, and biological plausibility — for consideration of causality in epidemiologic investigations. These were later modified by others and extended to experimental studies. My understanding is that, currently, the National Center for Environmental Assessment uses existing guidelines that address these issues to inform assessments. If confirmed, I look forward to working with the National Center for Environmental Assessment on these issues.

20. In developing chemical assessments, such as those in IRIS, there is a blending of science, policy and science policy assumptions and choices throughout the evaluations.

a. Do you agree that IRIS assessments should explicitly acknowledge and transparently convey the science and assumptions around the science (i.e., handling uncertainty) inherent in IRIS assessments?

Response: Strong science and transparency are essential to the IRIS Program and important to all of EPA's work. If confirmed, I look forward to working with the National Center for Environmental Assessment on this issue.

21. In the 2009 NAS committee you chaired issued a report recommending there should be one unified approach for dose- response modeling. Unfortunately, such an approach may not always consider the millions of dollars of research that have been invested to explore the mechanisms of action of individual chemicals. Significant activities, coordinated by the Alliance for Risk Assessment, have been undertaken since 2009 to broaden the understanding of dose-response and to link different approaches to conducting dose response to problem formulation. This has resulting in more than 30 published case studies, illustrating qualitative categorization, quantitative screening and in-depth assessments.

a. Do you support linking dose response to problem formulation such that the complexity of the dose response approach is "fit for purpose" and reflects the range of decision options and likely regulatory impacts?

b. Do you believe that any approach implemented needs to put chemical specific information and test data ahead of standardize approaches?

c. Will you support an approach the puts chemical specific information and test data ahead of standardized approaches in the IRIS program?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that our work reflects the best possible science.

22. In the past you have suggested, in an NAS report you chaired, that information on nonchemical stressors should be incorporated into assessments and EPA should put further research dollars into evaluating the interactions between chemical and nonchemical stressors.

a. Considering the struggles ORD is having simply evaluating chemical stressors in the IRIS program, do you believe that ORD has the staff, with requisite qualifications and financial capacity, to also take on evaluations of nonchemical stressors?

b. Shouldn't ORD first convince Congress, NAS, and all other stakeholders that they can appropriately evaluate chemical stressors before broadening their scope?

Response: If confirmed, I look forward to further exploring this important issue with scientists within and outside of the agency.

23. As noted in "Science and Decisions: Advancing Risk Assessment" (NRC, 2009) "... formal consideration of numerous simultaneous chemical, physical, and psychosocial exposures with evaluation of background disease processes and other

dimensions of vulnerability could quickly become analytically intractable if the standard risk-assessment paradigm is followed, both because of the computational burden and because of the likelihood that important exposure and dose-response data will be missing. That points toward the need for simplification of risk- assessment tools in the spirit of iterative risk assessment..."

a. Since the NAS 2009 report there have been significant advances in the development and application of tiered, iterative tools for cumulative risk assessment, including development by the World Health Organization of a formal framework for risk assessment of combined exposure to multiple chemicals. Do you support use of this WHO framework? If not, why not?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

24. Currently the staff in the IRIS Program are the sole arbiters of determining whether and to what extent draft IRIS assessments should be revised to reflect input from peer reviewers and the public. EPA's own Scientific Advisory Board has recommended the use of a "monitor" or "editor."

a. Can you commit to ensuring that a 3rd party, independent of the IRIS Program, is tasked with ensuring that EPA staff have sufficiently considered and responded to peer reviewer and public input before assessments and other documents are finalized?

Response: Public comment and robust expert peer review is an important part of the agency's scientific work, and responding to public and peer review comments is an important step in completing a scientific product. It is my understanding that responses to public comments are documented in an appendix to each IRIS assessment so that interested parties can judge the adequacy of the response. If confirmed, I look forward to working with scientists in the agency to explore this issue further.

25. In previous comments on IRIS reform, you said that EPA's IRIS program is in "crisis" and is in need of reform while further stating "the sleeping giant is that EPA science is on the rocks ... if you fail, you become irrelevant, and that is kind of a crisis." Further, you admonished, "You can't fail at this time."

In response to a question you said, "We owe it to the American public, we owe it to the scientific community... to have risk assessments based in sound science. It would be better to do it right than destroy the credibility of the process."

The NAS report on formaldehyde was critical of the process as well as the underlying science that EPA used in its draft assessment. Your October 2011 testimony emphasized not only the importance of the process but, more importantly, the scientific conclusions or scientific content of the IRIS assessments.

a. Given the significance of this risk assessment to the scientific process and for restoring the public confidence in EPA's science, it is imperative that you commit to having the NAS retook at the next iteration of the formaldehyde IRIS assessment. Can I have your assurance that this peer review will take place?

Response: If confirmed, I will work to implement the recommendations of the NAS Formaldehyde Committee, not only for formaldehyde but for all IRIS documents. While I can assure there will be rigorous peer review of the revised formaldehyde document, I believe it is premature for me to provide assurance that another NAS committee will be convened specifically to re-review formaldehyde. I do look forward to working closely with the NAS to continually improve the quality of EPA science.

26. EPA, at the urging of stakeholders, will convene a scientific workshop on formaldehyde in the first half of 2014. Three key issues have been identified for discussion. I am concerned that this workshop will be similar to typical EPA science workshops of the past where the agency solicits input from a variety of stakeholders, irrespective of their qualifications, listens politely and without comment' and provides no resolution or feedback. Quite frankly, that is a waste of time and resources. I want to see difference in interpretation of the data, particularly from the epidemiological studies, narrowed. It is my hope that a robust dialog will help accomplish that. EPA staff should be engaged participants in the dialog, not mute listeners and I suggest EPA engage a professional facilitator and have the proceedings of the workshop published. Will you commit to be personally involved in the development and conduct of this workshop and ensure that the right scientists with the relevant subject matter expertise are at the table?

Response: Workshops to address important scientific issues, such as those related to assessing the health risks of formaldehyde, can help the agency in conducting its work. If confirmed, I look forward to working with the National Center for Environmental Assessment to ensure that this workshop is successful and includes experts with the appropriate background and knowledge.

27. The EPA workshop is timely, important at both the scientific and policy levels, and deals with scientific challenges of the highest order. How will you assure EPA integrates high quality information to help inform regulatory decisions for formaldehyde that presents complex challenges? How will EPA conduct a thorough, state-of-the-art WOE evaluation of the entire database?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

28. If you are confirmed, what commitment will you make to ensure EPA's scientific content and scientific conclusions are sound in light of the series of significant scientific shortcomings that the NAS Formaldehyde report identifies and the subsequent recommendations put forward?

Response: EPA has initiated a number of changes in response to the NAS Formaldehyde report. At the present time there is an NAS panel examining the overall IRIS process. If confirmed, I look forward to receiving the findings of the NAS and taking any necessary steps to address shortcomings and continually evaluate and improve the process.

29. As you know, Congress directed EPA to contract with the NAS to review the cancer and non- cancer IRIS assessments of inorganic arsenic. It is our understanding that a senior scientist in the IRIS program stated publically in a meeting that any recommendations from the NAS would be unlikely to change the agency's views on the arsenic IRIS assessment If confirmed, are you prepared to effect organizational and staffing changes to ensure that scientific integrity characterized by objectivity, transparency and scientific rigor is restored?

Response: I am not aware of any specific details relating to this purported statement by the senior scientist. As an active participant in NAS activities and Chair of multiple studies, I have tremendous respect for the work of the Academy. I can assure you that, if confirmed, I look forward to meeting with the NAS committee and working to implement recommendations they may provide to improve the IRIS assessment for both cancer and non-cancer effects of inorganic arsenic. I will also devote myself to ensuring integrity of all IRIS assessments and working with the staff to continually improve quality, objectivity, and transparency.

30. What are your views on how best to use systematic review as a tool to identify and review the body of scientific literature pertinent to a risk assessment of a chemical or substance? It is our understanding that the systematic review method developed by Dr. Birnbaum at the NTP and planned to be used by EPA IRIS automatically codes studies in the literature funded by industry as biased. That would mean that industry studies would not be given the same weight as other studies possibly funded by other organizations. How do you view this practice? How can you justify automatically ascribing bias to studies from or funded by industry, ignoring their scientific merit? Couldn't this distort the science by leaving out reliable and sound scientific studies?

Response: Systematic review of epidemiologic studies provides a valuable way to consider the findings from multiple investigations in evaluating the evidence for adverse effects. The review process also provides a framework for selection of studies for inclusion. The consideration of studies should be driven by the quality of the science. The systematic review process can address potential questions about investigator bias can still include studies that may be funded by industry. In risk assessment the systematic review process should be as robust as possible, with clear and transparent criteria for inclusion and exclusion of studies. Funding source alone should not be the basis for the decision to exclude a study from consideration. A full examination of study quality and potential bias is essential.

a. Others have pointed to different sources of bias, such as publication bias, which creates incentives, including increased likelihood of funding, toward studies that report positive associations; what are your views on this and similar concerns and how do you plan to take these kinds of bias into account?

Response: The issue of publication bias can be challenging. It is recognized that positive studies are more likely than negative studies to be published in peer reviewed journals. There may be many reasons contributing to this trend, including investigator choice not to submit negative studies and other design considerations that may contribute to the failure of a study to achieve statistically significant positive results. As a peer reviewer for many journals, I have never recommended rejection of a paper solely because of a negative result. Nor am I aware of any editors or editorial guidelines that recommend rejection of epidemiology studies with negative results. However, recognizing there may be a publication bias I believe it is very important that the systematic review process cast a broad net to be as inclusive as possible and include well conducted studies with both positive and negative findings.

31. The recent NAS interim report on inorganic arsenic states, "EPA proposes to use linear low-dose extrapolation as the default for cancer and non-cancer effects." This is in contrast with the EPA cancer guidelines, which supports the use of mode-of-action to determine the shape of the dose- effect relationship. It is also in contrast with general mechanistic understanding of non-cancer dose-response relationships. What are your views on linear versus non-linear approaches to risk assessment? Do you think EPA should pursue the establishment of a threshold at low exposures if the data support such association?

Response: Understanding the impact of chemical exposures at extremely low doses is perhaps the most challenging issue in risk assessment. Unfortunately, for the large majority of chemicals there is currently limited information about mode of action and great uncertainty about the dose-response relationship. For carcinogens, the default continues to be linear extrapolation at low doses. For non-carcinogens the dominant default has been to assume the existence of a threshold and use a safety factor approach in the face of limited information. The "Silver Book" provides guidance on addressing the issues of thresholds and urges that EPA develop tools to quantify non-cancer risks. Establishing a population threshold is very challenging, particularly when considering the most vulnerable members of our population such as developing infants or the elderly. If there is strong data supporting a threshold it should be presented as part of the risk assessment. In general, risk assessments should present the fullest characterization of risks possible, presenting both cancer and non-cancer findings, and providing risk managers with both linear and non-linear model results where there is sufficient data.

32. As an epidemiologist, please describe how you think the body of epidemiology on a specific substance should be reviewed. For instance, many observers, including the NAS, have criticized EPA for giving too much weight to epidemiological studies of large populations exposed to inorganic arsenic, such as the Taiwan data, just because of the large number of subjects, while giving little credence to studies from the US that observe smaller populations, although the lifestyles, including nutrition, of the large populations are totally different from US lifestyle. Meta-analysis studies have been conducted of US populations that address the smaller number of study subjects, but EPA has ignored those studies. These meta-analyses provide evidence that the dose-response relationship used by NRC 200 I from Taiwan is not consistent with findings from the US, and is higher than what would be derived from studies of US populations. What is your view on

the use of meta-analyses as a way to integrate information from smaller studies and to provide a reality check on EPA risk calculations?

Response: Within the field of epidemiology there is currently a great emphasis on improving the methods and application of meta-analysis and systematic review. This was in part stimulated by the recommendations of the NAS Formaldehyde report. The current process for review and refinement of the IRIS arsenic document will be addressing the challenge of improving the presentation and consideration of epidemiological findings. I am optimistic that an improved process will be more inclusive of smaller studies and provide a more transparent scientific basis for the selection of the critical studies used to calculate risks.

33. Studies from places like Bangladesh and Taiwan involve populations with very different nutritional statuses than is found in the US. The NAS Interim Report notes the importance of taking account of these differences in applying these study findings to the US (at p.59). How would you extrapolate from those studies to make the data relevant to the US?

Response: I agree that cultural, nutritional, and exposure difference should be considered in assessing and managing risks to the U.S. population. If confirmed a look forward to examining the recommendations of the NAS committee and actively working with the IRIS program to address the questions regarding relevance to the U.S. population.

34. How do you view the intersection between epidemiology and toxicology? Many critics believe EPA has been overly reliant on epidemiology and deemphasized mechanistic research that provides guidance for dose-response calculations. Some EPA critics suggest that a reluctance to identify modes of action is a deliberate approach by EPA to allow it to use epidemiological data to validate their modeling.

a. What steps can you take to correct this bias, whether real or perceived?

Response: Toxicology and epidemiology are both essential if we are to understand and manage risks. Both types of studies have advantages and limitations, and the best approach is to improve how we consider the full body of evidence from both of these disciplines. While well conducted studies of human populations are considered the "gold standard" for assessing human health risks, toxicology provides important information when human studies are lacking or not possible. The large majority of IRIS risk assessments are based upon animal toxicology, including assessments of cancer risk, because the dose response data from most human studies is very limited.

I do not believe there is a bias against toxicology studies. If confirmed, I will work with risk assessors and other scientists to provide clear criteria for consideration of epidemiology and toxicology in the risk characterization process. I will also support continued research to improve the application of mechanistic data to risk assessment.

b. Science commentators have noted a concern about "normative science," which is defined as "information that is developed, presented or interpreted based on an

assumed, usually unstated, preference for a particular policy choice." [Lackey, Robert T. Normative Science. *Terra Magazine,* Oregon State University, Volume 8, Issue 2 (2013).] What steps will you take to ensure that EPA's science assessments on your watch do not include this kind of normative science?

Response: I do not believe that "normative science" is practiced at EPA, and the best approach to this concern is open and credible peer review throughout the scientific process. It also it is important to separate the scientific assessment of evidence from the ultimate policy decision that must consider other social and economic factors.

c. Another type of concern has been identified: "EPA's use of assumptions that it claims are 'public health protective,' which err on the side of overstating risk when data are lacking.... Such inflated risk estimates can lead to overly stringent regulations and can scramble agency Priorities because the degree of precaution differs across chemicals. How do you intend to guard against this problem? What are your views on the use of empirical data as a "reality check" on overly conservative risk assessments, particularly those resulting from modeling or extrapolation of data? How do you view the application of additional safety factors - particularly when they become cumulative- for sensitive subpopulations or policy considerations such as environmental justice?

Response: First, I believe that the fundamental mission of EPA is to protect public health, and therefore agree with approaches that are "public health protective". I also believe that the fundamental challenge in assessing chemical risks is a lack of data. Therefore, it is not really valid to say that the EPA assumptions "overstate the risks when data are lacking". For example, in the absence of data about a specific unrecognized health effect it may be the case that risks are underestimated. The current drinking water emergency in West Virginia is an example of the challenge of safeguarding public health when the data about health effects is limited. In the absence of data, safety factors provide a time tested public health strategy to safeguard communities.

I agree that more specific evidenced based approaches to safety factors and the protection of vulnerable subpopulations are needed. Also, risk characterization should include presentation of multiple modeling approaches to assist decision making and provide a "reality check" based on empirical data. Cumulative risk presents a difficult challenge. I support continued research to refine our methods of considering interaction of multiple stressors in risk assessment, particularly regarding sensitive populations and environmental health disparities.

35. The NAS 2008 Report: <u>Science and Decisions: Advancing Risk Assessment,</u> frequently referred to as the "Silver Book" strongly recommended that EPA should consider the regulatory impacts of its IRIS hazard assessments. Since then, EPA has proposed IRIS assessments, including the cancer assessment for inorganic arsenic, which would drive regulatory standards below naturally occurring background levels in soil and water. EPA national and regional managers were highly critical of the IRIS proposed 17x increase in the cancer slope for inorganic arsenic, saying the science was " detached from reality" and would have "disastrous consequences" for EPA programs including Safe Drinking Water and RCRA.

The NAS Silver Book urges EPA to perform extensive examination of risk management implications and options in the first phase of human health hazard assessments. It further recommends involving EPA national program managers (Air, Water, CERCLA, RCRA) in this early phase of assessment so that EPA can then use risk assessment to make more informed choices among those options.

Do you support this particular recommendation from the NAS Silver Book? Do you believe EPA's IRIS assessments must properly consider the "real world" regulatory and risk management implications of its hazard assessments?

Response: As Chair of the NAS Committee, I strongly support the recommendations of the "Silver Book". It is important that risk assessment be designed to address the needs of decision makers and risk managers. However, the risk management process should be recognized as distinct from the characterization of health risks. The ultimate decision on the application of risk information for risk management is a policy decision. Issues of feasibility and cost are essential components of the decision process and are not driven by dose response findings. The risk management decision must consider the "real world". The full process presented in the Silver Book is a continuum from problem formulation through risk management.

36. What is the cost of EPA's Hydraulic Fracturing study on the potential impacts of hydraulic fracturing on drinking water resources thus far? How long has the agency been engaged in the study? What has the agency done in terms of testing?

Response: To my knowledge, the work began in 2010 in response to a request from Congress. If confirmed, I will look into the budget of the EPA's study as well as the specific research projects.

37. Has the EPA done any testing in real time for sites that are being drilled now? My understanding is that the agency has tested several sites that were drilled years ago, which is a problem because EPA does not have a good baseline of information and there are other factors which could have caused contamination (agriculture, mining, etc.). How does EPA plan on overcoming the lack of good baseline information and ensuring no conclusions are drawn about hydraulic fracturing without first ruling out any other possible sources of contamination?

Response: Although I participated in a 2011 EPA SAB review of the study, I am not familiar with the specific details of EPA's sampling work, the availability of baseline information, or how the agency will use this information to draw conclusions about potential sources of contamination. If confirmed, I look forward to working with scientists in the agency to explore this issue further.

38. Has the agency has expanded the scope of the study beyond looking at groundwater? What is the full scope of what the agency is now studying? What are all the various pieces that will be included in the study? Were those asked for by Congress? If the study has been expanded, what justification does the agency have for doing so?

Response: I am not familiar with the specific details of the study including the scope, as it may have changed from the Study Plan that I commented on in 2011. If confirmed, I will support a scope that is responsive to Congress' request.

39. What has been the extent of EPA's work with DOE and USGS to date on the study?

Response: If confirmed, I look forward to gaining an understanding of how EPA has worked with other agencies to ensure that research efforts are done efficiently and effectively. However, at this time I do not know the extent to which EPA is working with other federal agencies on the hydraulic fracturing study.

40. How are you accounting for fracturing technology, as it is changing quickly and beneficially, as part of the study?

Response: I am not familiar with EPA's approach for staying up to date on changes in industrial practices related to hydraulic fracturing. If confirmed, I look forward to working with scientists in the agency to ensure that this study is based on the best available science.

41. There has been some controversy over methane leakage from shale development and hydraulic fracturing. But a recent study from the University of Texas that was published in the Proceedings of the National Academy of Sciences found that methane leaks from natural gas development were in line with EPA's data, which showed a leakage rate of only about 1.5 percent. There are several other studies, some of which found high leakage rates, but most seem to suggest that leakage is low and manageable. Based on your review of the scientific literature, what's your understanding of methane leakage from natural gas development, and do you see any environmental benefits of increasing natural gas production and use in the United States?

Response: I have not reviewed the National Academy of Sciences paper and cannot speak to the issue of methane leakage at this time. If confirmed, I will look into this issue.

42. Former EPA administrator Lisa Jackson said, 'I'm not aware of any proven case where the fracking process itself has affected water.' Secretary of Energy Ernest Moniz has said 'I still have not seen any evidence of fracking per se contaminating groundwater.' Interior Secretary Sally Jewell said she is 'not aware of documented cases' of hydraulic fracturing contaminating groundwater. I realize the EPA is currently studying this issue, but based on the evidence already available, do you agree with these officials' assessments?"

Response: I am not familiar with the details of the scientific literature, but will look into the issue if I am confirmed.

43. The increase in domestic energy production is due to the application of two proven engineering technologies- hydraulic fracturing and horizontal drilling. Hydraulic

fracturing has been used commercially since the 1940s and directional drilling has been around since the 1930s. Development of resources using these technologies is responsible for 2.1 million American jobs and this number is expected to rise to 3.9 million in 2025. Furthermore, tens of thousands of wells are drilled every year using the process, and we have seen over a million wells drilled in the US with no cases of groundwater contamination. Do you agree that hydraulic fracturing is critical to our economy and our national security? Do you agree that it is a proven technology that has been used safely for over half a century and can be used safely?

a. Are you aware of any cases where hydraulic fracturing has contaminated drinking water?

Response: Energy production is critical to our economy and our national security and hydraulic fracturing should be done in a manner that protects human health and the environment. At this time, I cannot speak to the level of safety associated with hydraulic fracturing, as it has not been my professional focus to date. However, if confirmed, I am committed to ensuring that EPA has all of the information available about the safety of the technology. As I mentioned during my hearing last month, from my own experience, having done many studies of groundwater contamination, I am not familiar with a specific case of drinking water contamination from hydraulic fracturing.

44. As part of the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water, the conference report stated that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

a. Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study? Do you believe it is the SAB ad hoc panel's role to peer review all of the study's reports and projects as part of the study?

Response: I believe that rigorous peer review is an important element to ensure the quality of the science. I am not familiar with the details of ORD's peer review plan for the study. If confirmed, I will look into this issue and support decisions that ensure valid and accurate data as well as transparency.

45. Also included in the conference report is the statement that "The Agency shall consult with other Federal agencies as well as appropriate State and Interstate regulatory agencies in carrying out the study..."

a. Are you aware of any other federal agencies currently being consulted in the study? Which agencies will you consult with should you be confirmed and head the ORD and lead the study?

Response: I am not familiar with the extent to which EPA is working with other federal agencies. If confirmed, I look forward to learning about how EPA has worked with other agencies to ensure that research efforts are done efficiently and effectively.

46. Recently, EPA Administrator Gina McCarthy was quoted as saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifers."

a. Do you agree with that statement?

Response: I am not familiar with the Administrator's statement. If confirmed, I will look forward to learning more about the issue.

47. This June, ORD announced it would abandon its flawed drinking water investigation in Pavillion, WY and would instead support a further investigation by the State of Wyoming.

a. Given the flawed science on display by the agency in Pavillion and ORD's withdrawal, will you exclude the agency's work and data prior to June 2013 from the agency's Congressionally-requested study on the relationship between hydraulic fracturing and drinking water? If not, why not?

Response: I am not familiar with the specific details of ORD's support of the Agency's Pavillion investigation. If confirmed, I look forward to learning about EPA's work in this area.

b. ORD abandoned its investigation, yet according to agency statements, continues to "stand behind its work and data." How can the agency reconcile these directly contradictory actions? How would you explain to the American people that continuing a flawed investigation is not worth taxpayer resources, yet the agency "stands behind" the work and data that it abandoned? If confirmed, will you correct the record and explain to the public that EPA does not stand behind flawed science?

Response: I am not familiar with the specific details of the agency's Pavillion investigation. If confirmed, I will look into this issue.

c. Are you aware of criticisms of EPA's work in Pavillion by other federal agencies? How would you respond to those criticisms?

Response: I am not aware of any specific criticisms from any agency.

d. How are ORD and the EPA regional office in Denver currently supporting the State of Wyoming's investigation?

Response: I am not aware of any specific details of the investigation.

48. Is there a reason, particularly as it relates to air science impacts (PM, ozone, etc.) that we don't see the agency using nonlinear threshold analysis? There are concerns that EPA's analysis is allowing the agency to count benefits that just don't exist, or otherwise set standards below naturally occurring background levels. We've seen this in chemical assessments as well, such as on dioxin and inorganic arsenic. How do we resolve the distance between theoretical benefits and empirical evidence?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

49. One of the most important responsibilities of the EPA Office of Research and Development is the development of health assessments for EPA's IRIS program. In September 2011, EPA issued its long-awaited "Toxicological Review of Trichloroethylene (CAS No. 79-01-6) in Support of Summary Information on the Integrated Risk Information System (IRIS)."

The IRIS Assessment contains a reference concentration ("RfC") of 0.0004 ppm (0.4 ppb or 2 J.Lg/m3) and a reference dose ("RfD") of 0.0005 mglkg/day for trichloroethylene (TCE). These are values that are considered by EPA to be protective for all noncancer critical effects. EPA's derivation of the RfC/RfD for TCE is based, in part, on Johnson *eta/.*, Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environmental Health Perspectives 111: 289-92 (March 2003).

The RfC/RfD is within the range of background concentrations of TCE in urban air. There is a significant ongoing dispute among the EPA regions as to whether and how this RfC/RfD derived from Johnson *et al*.should be the basis for a short-term TCE exposure limit at Superfund sites. Thus, the proper interpretation and use of this non-GLP study in risk assessment is a question of the highest priority to EPA's Superfund program.

As noted in the peer review of a recent EPA "TSCA Chemicals Work Plan" assessment of TCE which was highly critical of EPA's reliance on Johnson *et al/.*, "[o]ne of the fundamental tenants in science is the reliability and reproducibility of results of scientific investigations."

The peer reviewers noted:

- **At least two GLP-compliant studies conducted under both EPA and OECD guidelines have been unable to reproduce the effect seen by Johnson *et al.*, despite the participation in one of the studies by Johnson herself.**

- **The dose-response relationship reported in Johnson *et al.* for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.**

- **The congenital heart defect incidence in control animals in Johnson *et al.* was 86 times the historical control incidence in Charles River rats.**

- **As California EPA noted in declining to rely upon Johnson *et* al, "These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits. The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al.,2004)."**

Is EPA concerned that the TCE IRIS Assessment appears to rely on an irreproducible study result? Is there any effort underway to correct this Assessment? Does this information presented seem to indicate that the EPA's IRIS program is no longer "crisis" and is being based on the best available science?

Response: I am not aware of any EPA effort to review the IRIS assessment for TCE. EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that our work reflects the best possible science.

Senator James Inhofe

1. Dr. Burke, as head of the EPA's R&D Office, you are going to have responsibility for the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water. The conference report mandating the study state that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study?

Response: I am not familiar with the details of ORD's peer review plan for the study. If confirmed, I will look into this issue and support decisions that ensure valid and accurate data as well as transparency.

2. Dr. Burke, a few weeks ago the EPA Administrator was quoted saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifiers."

Do you agree with this statement?

Response: I am not familiar with the Administrator's statement. If confirmed, I will look forward to learning more about the issue.

3. Dr. Burke, you have served as a member of EPA's Science Advisory Board. The SAB serves an important function especially in regard to providing advice on EPA's study on hydraulic fracturing and drinking water.

a. In your capacity on the SAB, did you have an opportunity to review EPA's study plan?

Response: As a member of the Charter Board of the Science Advisory Board, I did review the study plan. I submitted written comments on July 5, 2011. These comments are part of the public record and are available on the SAB website. The comments were generally supportive of the study plan and included suggestions for reaching out to local health officials and improving the evaluation of potential health risks to communities.

b. Do you agree that all of the individual components of the study should be deemed highly influential scientific assessments?

Response: I am not familiar with the EPA practices regarding defining a study as a highly influential scientific assessment. If confirmed I look forward to working with the scientific staff and learning more about these designations and their impact on the peer review process.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 17 2014

OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510-6175

Dear Chairman Boxer:

Thank you for the opportunity to respond to the Questions for the Record following the December 17, 2013, hearing entitled, "Hearing on the Nominations of Rhea Sun Suh to be Assistant Secretary for Fish and Wildlife and Parks of the U.S. Department of Interior, Victoria Baecher Wassmer to be Chief Financial Officer of the U.S. Environmental Protection Agency (EPA), Roy K.J. Williams to be Assistant Secretary of Commerce for Economic Development of the U.S. Department of Commerce, and Dr. Thomas A. Burke to be Assistant Administrator for the Office of Research and Development of the EPA." The responses to the questions for Thomas Burke and Victoria Wassmer are enclosed. I hope that this information is helpful to you and the members of the Committee.

If you have any further questions, please contact me or your staff may contact Carolyn Levine in my office at levine.carolyn@epa.gov or (202) 564-1859.

Sincerely,

Laura Vaught
Associate Administrator

Enclosures

Questions for the Record
December 17, 2013 Hearing on the Nomination of
Victoria Baecher Wassmer
to be Chief Financial Officer of the
U.S. Environmental Protection Agency
Committee on Environment and Public Works
United States Senate

Senator Boxer

1. **Ms. Wassmer, can you describe how your background and experiences at the FAA and earlier at OMB have prepared you to be the Chief Financial Officer at EPA?**

   Response: I would bring to the role of Chief Financial Officer (CFO) of the Environmental Protection Agency (EPA) 20 years of proven professional experience in progressively high-profile positions, including 15 years of hands-on, practical financial management and leadership within the Federal government. My service to the Federal Aviation Administration (FAA), the Millennium Challenge Corporation, and Office of Management and Budget (OMB) has prepared me for this complex, invigorating opportunity by allowing me to learn firsthand the critical importance and practice of being a responsible, vigilant steward of the American taxpayers' dollars.

   Specifically, in regards to my experience at OMB and FAA, after completing graduate studies in public policy at the Kennedy School of Government, I spent six years at OMB. I gained experience as a policy analyst in the Office of Information and Regulatory Affairs before becoming a program examiner in the Transportation Branch. In these roles, I was responsible for overseeing management, regulatory, policy and budgetary issues over an array of agencies. I later joined the FAA as a manager and then Deputy Director in the Office of Budget. I went on to become a member of the Senior Executive Service and was named the Deputy CFO, responsible for managing the $16 billion annual budget that allows the FAA to achieve its mission of providing the safest, most efficient aerospace system in the world.

   In August 2011, I returned to the FAA as the Assistant Administrator for the Office of Finance and Management. Since then, I have overseen the transition of the agency's finance, acquisition, information technology, and region and center operations services into a single, integrated shared services model. I have also spearheaded agency reforms that ensure resources are properly managed and better optimized to drive cost reductions and financial accountability. Through our centralized approach for common financial services, my team and I have identified value-added financial strategies and performance measures that have realized cost savings, increased efficiency, and reduced duplication in order to better support our customers and the FAA mission. Our data-driven strategies helped the FAA identify approximately $637 million in FY 2013 budget reductions alone, of which approximately $320 million were through contract spending, travel, and other non-pay reductions. During my tenure, we also led the agency in achieving the Certificate of Excellence in

Accountability Reporting (CEAR) Award for the FAA's FYs 2011 and 2012 Performance and Accountability Report (PAR), marking the eighth and ninth time the agency has received this distinguished award. In addition, we led the FAA in receiving unqualified financial statements audit opinions from the agency's independent public accountants in FY2011, 2012 and 2013.

Combined with my formal education and leadership training, my practical experience has prepared me well to be the CFO at EPA.

2. **Ms. Wassmer, can you describe how, with your background and experiences working for the FAA, OMB, and with the Office of the Vice President's Millennium Challenge, you will provide a fresh perspective and how you will work to change, as appropriate, EPA's financial management systems?**

Response: If given the honor of serving as the Chief Financial Officer (CFO) of the Environmental Protection Agency (EPA), once I am a member of the EPA team, my first priority will be to use every means possible to identify the changes needed to improve the performance, integrity, and transparency of the EPA's financial management systems. As part of my immersion in the agency, I will meet with a range of internal stakeholders and external customers, review financial documents, and investigate existing practices, policies, and procedures to gain a comprehensive familiarity of the systems that are currently in place and to identify opportunities for improvement. While I cannot provide examples of specific changes I would make until I have an educated, hands-on understanding of the agency's current state, my goal and focus over the course of my appointment will be to make changes in the near-term that will expedite improvements needed to ensure the integrity of the EPA's financial practices while developing and implementing a long-term plan that will drive the continuous improvement of those practices. I will rely heavily on lessons learned and best practices gained over my 20-year career and specifically through my service to the Federal Aviation Administration (FAA), Office of Management and Budget (OMB), and the Millennium Challenge Corporation to apply a strategic, data-driven approach to implementing sound business practices that will ensure performance and accountability.

In my current work as Assistant Administrator for the Office of Finance and Management for the FAA as well as in my previous roles as Vice President of Administration & Finance/CFO for the Millennium Challenge Corporation and the FAA, I have been responsible for providing oversight and management for each agency's complex, multi-billion dollar appropriations and ensuring accountability to the American taxpayer for all laws, policies, and procedures. In each of these positions as well as in my role as Deputy Director of the Office of Budget at FAA, I have also spearheaded the reorganization of financial organizations and operations to optimize financial reporting, financial systems, internal controls, audit and accounting standards, budget formulation and execution, performance management and cost controls.

Regardless of the current health of a financial management system, my experience has taught me that the role of a leader is to ensure that the system remains on a continuous path of improvement. As with any process, something can always be done better. It is a matter of

proactively looking for those opportunities by tracking and analyzing meaningful data, listening to the feedback of stakeholders, and measuring performance against relevant targets. This is what I have done at the FAA, OMB, and the Millennium Challenge Corporation, and it is what I would do as CFO of the EPA.

3. **Ms. Wassmer, one of the roles of the Chief Financial Officer is to oversee EPA's goal setting process. Can you explain how you would ensure that EPA is working every day to enhance safeguards for pregnant women, children, and other vulnerable populations?**

Response: If confirmed as the Chief Financial Officer (CFO), goal setting would be an important responsibility of mine and integral to Agency decision making. I look forward to working within EPA to set forth strategic direction and consider tough choices needed to meet our mission. As I have done at FAA and in previous positions, I will work with the relevant office(s) at EPA to use a data-driven approach to inform EPA's planning process to ensure that the appropriate level of safeguards are in place for all of the American public, including sensitive populations.

4. **Ms. Wassmer, can you describe what in your background best prepares you to be EPA's Chief Financial Officer?**

Response: Over my 20+year career since graduate school, I have worked in all levels of the government's financial arena – from a new analyst to a seasoned Assistant Administrator for Finance and Management. I understand and have successfully shouldered the important responsibility, the increased scrutiny, and the critical accountability that comes with being a Chief Financial Officer (CFO) and ensuring the effective, judicious execution of an agency's budget. Yet, as with everyone, I am the sum total of my experiences. Many of those experiences have taught me what works in a particular situation, while others have shown me what does not work. In my professional life, the worker, the employee, the colleague, the leader I am today was formed by each of those experiences, and it is that, more than anything, which has best prepared me to successfully take on the role of the Environmental Protection Agency's CFO.

Growing up, my parents instilled in me through their own careers and actions the belief that public service is a noble calling and that it is an honor to be in a position where you can serve others. In my first jobs out of college as a job developer for tradeswomen and project manager in Chicago, I learned how you can help others excel by ensuring they have the opportunity to be successful. Through my work in South Africa, I learned that if you engage the people who are most affected by a problem, their input will often help you identify the best solution. It also reinforced my belief that given opportunities, individuals can achieve great heights and that everyone deserves to be treated with dignity and respect. During my time at OMB, I learned from master senior executives and policy officials who showed me each day through their actions that integrity is always a personal option and that you should always strive to do the right thing, even when it is the harder or unpopular path. At the Millennium Challenge Corporation, I learned the true value of a dollar, and how far you can stretch it if you optimize your resources and focus on what is truly needed, not what is most wanted. I was reminded that a fresh perspective can help you identify new ways to work

smarter and achieve cost savings that can be reinvested in the programs that make the biggest difference.

As the Assistant Administrator for the Office of Finance and Management, I stood-up a new, first-of-its-kind shared services organization that today provides efficient and effective enterprise-wide business solutions and services to customers across the FAA as well as to the Department of Transportation and other government agencies. This has been an incredible learning experience. It taught me how to work with many diverse senior executives with differing opinions and personal agendas and how to facilitate consensus for the adoption of the best possible decisions for the agency. It also reinforced my belief that as the leader of an organization, you are ultimately responsible for the decisions made and the quality of the services provided. So, you have to set the bar high, make your expectations clear, continually take the pulse of your organization, proactively identify and try to fix what does not work or what could be improved, put reliable systems in place that measure performance, be open to a course correction, and help make the people you work with and the people you work for successful.

While I could not begin to list everything I have learned and been taught over the course of my career, I have a deep understanding of what it takes to be a leader in a government agency and to be a responsible steward of the taxpayers' resources. I will bring these experiences with me if I am given the opportunity to serve as the CFO of the EPA, and I will work every day to restore and ensure the integrity of the agency's financial management systems and to earn the trust of you and the American taxpayers.

5. **Ms. Wassmer, one of the EPA Chief Financial Officer's responsibilities is to be the agency audit follow-up official responsible for agency-wide audit resolution and ensuring action officials implement corrective actions in response to OIG recommendations. Do you agree that, if confirmed, you will work with agency officials to ensure that appropriate actions are taken to implement corrective actions in response to OIG recommendations?**

Response: I respect the Inspector Generals' independent oversight of agency programs and operations. I believe an IG's mission to promote efficiency, effectiveness, and prevent and detect fraud, waste, and abuse aligns with a Chief Financial Officer's ethical and legal responsibility to ensure sound and proper use of the American taxpayers' dollars. If confirmed, I will work with the EPA's OIG and program and regional offices, as appropriate, to agree on and implement appropriate corrective actions as expeditiously as possible.

Senator Vitter

1. **Are you familiar with the criminal case against John C. Beale? As you should know, Beale was a career civil servant that bilked the agency for millions in unearned bonus pay, unauthorized travel, and by simply being paid for work he did not do. As the chief financial officer for the agency, it will in large part be your responsibility to develop and implement new systems to protect against this sort of fraud in the future. Please share with the Committee the steps you will take in your first 100 days to reform the agency and prevent future fraudulent acts.**

   Response: I have only seen press coverage and early warning reports issued by the Inspector General in December that were prepared at your request. Based on what I have seen, strengthened internal controls and careful monitoring of those controls would deter such conduct in the future and, if detected, end it more quickly and effectively. I take very seriously my responsibility to be a trustworthy steward of taxpayers' dollars. If confirmed, I will review the facts of the incident and the actions EPA has completed or plans to complete to ensure that ineffective controls, which may have failed to prevent Mr. Beale's fraud, are addressed swiftly and that compliance is monitored closely.

2. **In the case of John Beale, it appears that he could not have been able to accomplish his fraud against the American taxpayer without the assistance, either knowing or unknowing, or other EPA staff. For example, the Committee has learned that Robert Brenner was often the one who approved Beale's requests for bonuses and that Beth Craig approved his travel. Have you had the opportunity to review the facts of this case? Do you concur with my assessment that others at the agency participated, perhaps unknowingly, in Beale's fraud? What do you plan to do in your position as CFO to ensure that EPA employees are not bilking the taxpayers out of millions?**

   Response: I have not had the opportunity to review the facts of this case in detail. However, if confirmed, I will conduct a thorough and expeditious review of the facts and the actions EPA has completed or plans to complete to ensure the appropriate internal controls and compliance monitoring are in place to prevent the fraud Mr. Beale perpetuated. I also will ensure the OIG receives my full cooperation in its ongoing investigation.

3. **In the case of John Beale-did you know that he was still on pay roll AFTER his manager-Gina McCarthy-believed he had retired from the agency? How can something like that happen? Do you agree with me that such a disconnect is unacceptable?**

   Response: Again, I am not familiar with the details of this case. If confirmed, I will review the facts of the incident and ensure that EPA has taken or takes the necessary actions to prevent future fraud such as this.

4. **Are you aware of the fact that the EPA Inspector General has identified "Workforce Planning" as a serious management and performance challenge for the agency? Are you aware of the fact that according to the EPAIG, EPA currently does not identify**

the essential functions of staff based on data? Do you agree with me that a failure to identify essential agency functions based on data is a serious failing? Wouldn't the Harvard School of Public Policy frown on such a shabby state of affairs?

Response: I can assure you that I value the prudent use of sound, reliable data to inform decisions. In fact, throughout my career, I have relied heavily on data-driven approaches to make strategic business decisions at the corporate level. I am aware of the Inspector General's work on this important issue and understand its concerns regarding workload planning at EPA. If confirmed, I will review the issue and the actions EPA has completed or plans to complete to improve workload planning across the Agency so I can make a more informed decision regarding the appropriate next steps to move the Agency forward on this issue.

5. **Are you aware of the fact that despite prodding from GAO and the IG, EPA has not developed analytical methods or collected data to measure its workload and the corresponding workforce levels necessary to carry out that workload? How do you intend to remedy that?**

   Response: I respect the Inspector Generals' and Government Accountability Office's independent oversight of agency programs and operations. Their work to promote the efficient and effective use of the American taxpayers' dollars aligns with a Chief Financial Officer's duty to be a responsible steward of those resources. I am aware of the OIG and GAO reports and understand their concerns regarding workload planning at EPA. If confirmed as CFO, I will take a close look at this issue so that I can determine the appropriate next steps to drive the Agency's progress on data-driven workforce planning.

6. **Are you aware that when the EPW Committee asked EPA how much money the agency spent to conduct the watershed assessment of the Bristol Bay Watershed in Alaska, EPA admitted to my staff that they had no way of calculating the amount of in house resources dedicated to the effort? Do you find such a state of affairs acceptable? If not, will you commit to me today that as the CFO you will develop a process that will require the agency to know how much taxpayer dollars are being spent on agency activities?**

   Response: I was not aware of this issue until recently, and I am not familiar with the details. However, in my experience, cost accounting can provide useful financial management data to inform decisions to allocate budget resources, initiate or modify programs or projects, improve efficiency, and evaluate performance. If confirmed as CFO, I will review the issue thoroughly and take the appropriate action to expeditiously respond to your concern.

7. **As you may know, there have been 3 OIG reports on EPA justification for workforce level with the first being released on December 20, 2010, the second on September 14, 2011 and the last on August 30, 2013. Over the span of 3 years these reports have come to the conclusion that EPA is not meeting the requirements set by Title 5 CFR Part 250.202 the *Human Capital Assessment and Accountability Framework*, which states that**

workforce planning systems include a workforce analysis process that identifies the size and characteristics of the workforce needed to meet organizational goals. Contrary to this requirement EPA has not conducted the necessary workload analysis to determine the correct number of FTEs needed to specifically carry out the most essential parts of its mission. EPA has not done so for 20 years and still does not do so as of 2013. If confirmed as EPA's next CFO, will you commit to implementing a system can accurately model the workforce needs of the agency.

Response: As I stated previously, I assure you that I value the prudent use of sound, reliable data to inform decisions, and I have relied heavily on data-driven approaches throughout my career to make strategic business decisions at the corporate level. I am aware of the OIG reports and understand its concerns regarding workload planning at EPA. If confirmed as CFO, I will take a close look at the specifics and determine the appropriate next steps to move the Agency forward on this issue.

Questions for the Record
December 17, 2013 Hearing on the Nomination of
Thomas Burke to be Assistant Administrator of the
Office of Research and Development, U.S. Environmental Protection Agency
Committee on Environment and Public Works
United States Senate

Senator Barbara Boxer

1. Dr. Burke, do you agree that the Environmental Protection Agency (EPA) should use the current, best available science when making decisions on how to best protect human health and the environment, including implementing the recommendations of the National Academy of Sciences (NAS)?

Response: I agree that EPA should use the most current and best available peer reviewed science to inform decisions on protecting health and the environment. As chair and member of several National Academy of Sciences studies examining EPA science, I also agree that the agency should be responsive to the recommendations of the Academy and work to implement them to the best degree possible.

2. Dr. Burke, can you describe how your experiences on numerous NAS Committees and EPA science advisory councils, including the EPA Science Advisory Board, have prepared you to lead scientific research and development at EPA?

Response: I have worked closely with the agency as a member of the Science Advisory Board and member of the Board of Scientific Counselors. I have also served on the Board on Environmental Studies and Toxicology of the National Academy of Sciences and chaired a number of major Academy studies of EPA science. This experience has given me a strong understanding of the strengths and challenges of the EPA Office of Research and Development, and has provided me a valuable perspective of the views of a broad range of EPA stakeholders including business and industry, state health and regulatory agencies, academia, and community and environmental advocates.

Senator David Vitter

1. During the December 17, 2013, nominations hearing you committed to making data and information that underlies scientific studies used to justify EPA rulemakings available to the public. However, when it comes to most regulations under the Clean Air Act, the EPA has a practice of withholding underlying data, making it impossible for Congress and the public to fully understand the scientific underpinnings of major federal regulations. How will you reconcile EPA's current practice of withholding underlying data? How will you ensure that EPA's scientific work is objective and reproducible?

Response: Transparency and scientific integrity are very important to the agency's work. I understand that EPA has taken appropriate and substantial steps to increase transparency and public access to information. However, it is essential to protect the privacy of individuals who have served as subjects in studies and their personal health information. If confirmed, I intend to continue the agency's ongoing efforts to ensure that scientific and technical information that is intended to inform or support agency decisions continues to be based on the best available science.

2. Do you believe it is a conflict of interest for a researcher to receive funding from the EPA to conduct research, and then sit on exclusive panels for the agency making decisions based on the very same research?

Response: I believe it is important to have a balanced perspective in any review of research results and findings. Receiving funding from EPA should not disqualify outstanding scientists from participating in scientific panels however it is important to have strong and transparent measures to identify conflicts of interest. In my experience, science advisors may provide recommendations regarding scientific evidence but are not "decision makers" for the agency.

3. Isn't it correct that you and at least one of your close colleagues, Dr. Jonathan Samet, have received millions of dollars in research grants from the agency? If so, how many EPA research grants have you received? Please describe the scope of the research, which person and office at EPA authorized the grant, and the amount of the grant.

Response: Dr. Samet is a former colleague; he left Johns Hopkins in 2008 to take a position at the University of Southern California. Although we worked together on many academic activities, I was not a co-investigator in any of his EPA funded research.

The only major research grant I have received from EPA was a highly competitive Science to Achieve Results (STAR) grant in 2008 from the ORD National Center for Environmental Research entitled "Longitudinal Indicators of Policy Impact on Pollution, Exposure and Health Risk" The amount of the award was $499,961. I received funding from EPA Region 3 through a cooperative agreement in 1994 to address community environmental health concerns in South Philadelphia. The project was entitled "Pilot Multi-Media Environmental Health Characterization of South and Southwest Philadelphia" and the total funding was $519,000.

4. EPA research grants are supposed to be awarded in an unbiased and merit-based fashion. However, concerns have been raised that EPA summarily awards the same applicants the limited number of grants. Moreover, Dr. Burke, along with several of his colleagues at the Johns Hopkins University have received numerous EPA research grants. To ensure a competitive and neutral grant process, will you commit to acting without bias or favoritism in distributing EPA research grants?

Response: If confirmed, I will work to ensure that the research grant process is competitive and that the criteria for scoring the applications are clearly presented and transparent.

5. In recent years, the EPA Inspector General (IG) and the Government Accountability Office (GAO) reported instances where EPA grants have been awarded with no public notice, competition, or accountability. Will you commit to adopting all of the IG and GAO's recommendations regarding EPA's grant programs?

Response: I take seriously the role that the Inspector General and Government Accountability Office play in assessing the accountability of government programs, and if confirmed, I would welcome their recommendations. While I am not familiar with reports referenced in this question, if confirmed, I commit to reviewing the recommendations of the IG and GAO and giving them due consideration.

6. Francesca Grifo, former senior scientist and director at the Union of Concerned Scientists was recently appointed to serve as EPA's Scientific Integrity Officer within the Office of Research and Development. If confirmed, how do you intend to work with the Scientific Integrity Officer?

Response: As I mentioned in my opening statement, I have a deep respect for the work of the agency scientists and I believe science is the "backbone" of EPA decision-making, and has been the foundation of our nation's environmental progress over the past four decades. Science should be credible, transparent, and inclusive. If confirmed, I look forward to working with Dr. Grifo to see that the agency's Scientific Integrity Policy is fully implemented across the Office of Research and Development and EPA as a whole.

7. Are you familiar with Francesca Grifo, EPA's recently appointed Scientific Integrity Officer? Do you believe there is any reason to be concerned that Dr. Grifo's work at the Union of Concerned Scientists may affect her ability to carry out the responsibilities of the Scientific Integrity Officer?

Response: Although I do not know Dr. Grifo personally, I have reviewed her vitae and believe that her training and experience, including her work with the Union of Concerned Scientists, provide her with strong credentials to serve as Scientific Integrity Officer. If confirmed, I look forward to working with her to ensure the integrity of EPA science.

8. In promulgating National Ambient Air Quality Standards (NAAQS), EPA has repeatedly relied on studies that are based on individual cohort data collected in the early 1980s. In 2004, NAS cautioned against relying solely on these studies because of

the potential problems given that "cohorts were established decades ago, and some critical data items, including residence history, smoking rates, dietary factors, and other potential confounding and modifying factors, have not been updated." Do you agree with the NAS's caution against using studies that rely so heavily on outdated cohorts? Will you commit to reviewing this issue and reporting back to the Committee with specific guidance on how you intend to use such studies in setting standards and assessing risk?

Response: EPA's work to protect public health and the environment through programs such as promulgating National Ambient Air Quality Standards needs to be based on strong science. The NAAQS program is very important, and if confirmed, I look forward to reviewing this issue and working to ensure that the Integrated Science Assessments that provide the foundation for NAAQS decisions reflect the best possible science.

9. In the Office of Management and Budget's 2013 report on benefits and costs of federal regulations, over 80 percent of the claimed monetized benefits of all federal regulations were based on PM2.5 reductions. However, the report listed six major uncertainties, including a core uncertainty that PM2.5 may not cause the increased risk of mortality at lower concentrations.

a. Do you agree that these uncertainties are significant within the context of cost-benefit analysis?

b. Do you believe that EPA should address these uncertainties by developing integrated quantitative uncertainty analyses?

c. Will you commit to conducting this type of uncertainty analysis in the upcoming ozone NAAQS review?

Response: EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflect the best possible science.

10. OMB Circular A-4 requires key uncertainties to be disclosed and quantified to the extent possible to inform decision makers and the public about the effects and uncertainties of alternative regulatory actions. However, EPA has a practice of excluding and failing to quantify key uncertainties in the cost-benefit analysis of rulemakings. Will you commit to following all OMB circulars and guidelines? How will you ensure that key uncertainties are included and quantified in the cost-benefit analysis of EPA rulemakings?

Response: While I am not familiar with the specific requirements of that OMB circular and how it relates to the duties of ORD, if confirmed, I would certainly commit to follow all applicable OMB circulars and guidelines and to support the broader agency's efforts to comply with any such requirements. A big part of the ORD mission is to help provide information to fill key data and science gaps which can help to more fully characterize

uncertainty. If confirmed, I will work very hard to provide the agency with the tools and data necessary to deal with uncertainty in our regulatory analyses.

11. In FY2013, ORD received approximately $725 million in new appropriations and had $150 in unobligated balances. Yet, no one knows exactly how these funds are used or whether they are being used most efficiently to produce beneficial gains. In effect, EPA has no way of evaluating the environmental "bang for the buck" for each ORD research program. Will you commit to providing Congress an accounting on the costs and potential and actual beneficial gains of each ORO research program? If confirmed, how will you allocate spending in the Office of Research and Development?

Response: I am not familiar with the details of ORD's budget. If confirmed, I look forward to reviewing this issue to ensure that the resources are being utilized prudently and are focused on the priorities important to supporting the agency's mission.

12. The psychologist Brian Nosek and colleagues recently wrote: "Publishing norms emphasize novel, positive results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that elicit positive results and ignore negative results." Therefore, it seems that there is less of an emphasis on replication of findings to ensure scientific integrity than developing novel findings.

a. Do you believe that there is publication bias that leads to greater publication rates of studies reporting positive results compared to studies showing no relationship?

Response: Yes, I agree that there is a bias toward greater publication of positive studies. There may be many factors that contribute to this, including a lower submission rate by investigators when study results are negative and the possibility that weaknesses in study design may contribute to a higher likelihood of negative results.

b. Considering the likelihood of a possible publication bias by journals and a possible bias toward funding positive results by federal agencies, how do you recommend EPA consider this bias in weighing positive and negative studies?

Response: EPA should consider all relevant well-conducted and peer-reviewed studies, regardless of whether they are positive or negative, and include clear criteria for inclusion and exclusion of studies. Review and assessment of studies should be based upon the quality of the research, including study objectives and design, statistical power, presentation of the findings and conclusions, and consideration of study limitations, uncertainty, bias and confounding.

13. The scientific integrity of EPA's hallmark IRIS program has been questioned by Congress as well as the National Academy of Sciences (NAS). While Dr. Ken Olden is working to bring new leadership to the program, there is much more work that needs to be done.

a. Can you commit to ensuring that all draft and final assessments released by the IRIS program are consistent with the recommendations of the NAS Formaldehyde committee which recommended changes for all IRIS assessments, not just formaldehyde?

Response: My understanding is that the IRIS Program has been implementing the recommendations using a phased approach, consistent with the advice of the National Research Council (NRC), making the most extensive changes to assessments that are in the earlier stages of assessment development. Additionally, in July 2013, EPA announced enhancements to the IRIS Program that will improve the science quality of assessments, improve the productivity of the Program, and increase transparency. These changes are consistent with the NRC recommendations. If confirmed, I look forward to working with the National Center for Environmental Assessment.

b. Science has advanced significantly over the last 25 years. Will you ensure that as part of the improvements in the IRIS program, the Agency will move away from outdated default assumptions and instead always start with an evaluation of the data and use modem knowledge of mode of action -- how chemicals cause toxicity- instead of defaults?

c. Do you agree that standard protocols should be developed to enable all studies to be independently judged based on their quality, strength, and relevance regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

d. To further improve the IRIS Program, can you commit to revising the way hazard values are presented to the public to ensure that critical science policy choices are transparently presented and not comingled with scientific assumptions?

Response: EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflects the best possible science and that information is communicated in a transparent manner.

14. While health protection is often seen as the responsibility of EPA risk managers, when it comes to scientific assessments, the job of a risk assessor or toxicologist should be to produce assessments that are predictive of risks.

a. Do you agree that the role of the IRIS program is to identify values that are predictive of the potential health risks rather than those that provide the most conservative (lowest) value?

b. Will you support an approach to chemical assessment that results in hazard values that are predictive of actual health risk?

Response: IRIS assessments are designed to be scientific reports that provide information on a chemical's hazards and, when supported by available data, quantitative toxicity values for cancer and non-cancer health effects. EPA's work to protect public health and the environment needs to be based on strong science. I look forward to reviewing this issue and working to ensure that the scientific foundation for EPA decisions reflect the best possible science.

15. It is my understanding that internally the IRIS program no longer relies on definitions that are still publicly used (for example, the definition of the RfD and the meaning of confidence values in IRIS), yet EPA has never used any formal stakeholder or public or peer review process to implement these changes. Instead EPA seems to be relying on a 2002 review received from EPA's Risk Assessment Forum Technical Panel, and staff appear to pick and choose which suggestions they will follow and which they will not implement.

a. Will you commit to engaging stakeholders before changes to critical definitions and methodologies in the NAAQS and IRIS program are made?

Response: Yes, if confirmed, I will review the definition of the RfD and the confidence values.

16. Currently, when developing hazard values for exogenous exposures the IRIS Program does not consider natural environmental levels of chemicals, e.g., exposure to minerals from geologic formation, exposure to off-gassing from foliage, or levels naturally produced by the human body as part of its metabolic processes.

a. Do you agree that chemicals associated with the body's natural metabolic processes should be addressed specifically and separately in the development of a hazard value?

Response: This is an important consideration in understanding and managing incremental risk from environmental exposure. Since there are many natural products of metabolism that may have toxic effects if they are out of balance, the fact that they are naturally produced does not make them "safe" at all doses.

b. What is your position about addressing natural environmental chemical levels as distinct from background man-made emission?

Response: I believe that these are important considerations that should be presented as part of the problem formulation prior to undertaking a risk assessment. However, health based regulatory standards do not distinguish between natural occurring and man-made sources. Addressing incremental risks above background is an important consideration in risk management and the determination of "acceptable" risk in regulatory decision making. Reducing risks below background levels may not always be technically feasible.

c. Do you agree that IRIS hazard values should be able to pass a reality check and accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels?

Response: I cannot agree without more information about the specific pollutant of concern. The adverse effects of hazardous agents are not driven by whether or not they are "naturally" occurring. For example radon is known to increase risk of lung cancer. The source of the exposure does not impact the dose at which an adverse effect is observed. Natural occurrence and background levels are more appropriately considered in the risk management strategy.

17. There is a pressing need for priority setting when it comes to chemical evaluations within ORD and throughout EPA.

a. Can you commit to developing a clearly articulated prioritization process for high priority IRIS assessments that benefits from, and is responsive to, engagement from all stakeholders? Will you ensure coordination with other EPA program offices?

Response: I understand that EPA has previously committed to the Government Accountability Office that it will better describe for internal and external stakeholders and the public the nomination and selection process for chemicals for IRIS toxicity assessments, including the rationale for not selecting nominated chemicals for the full IRIS assessment. If confirmed, I look forward to working with scientists in the National Center for Environmental Assessment on this issue.

18. A 2011 GAO report recommended that EPA needed a more coordinated approach to managing its laboratories. In 2013 a National Academies (NAS) panel began reviewing EPA's laboratory capabilities. If the NAS study and EPA's own review substantiates that unnecessary and costly redundancy do indeed exist, do you commit to expeditiously undertake appropriate actions to consolidate or close labs, and reduce redundant staff?

Response: I understand that EPA has undertaken to do a study of the laboratory enterprise and has engaged the National Academies as part of this process. If confirmed, I will look into the progress of this effort.

a. Can you commit to developing a plan to undertake research in order to build the datasets necessary to establish scientific confidence for regulatory use of a tiered, risk-based approach for using high-throughput/high-content screening assays for safety evaluations (looking to approaches already developed such as the from the Hamner Institute)?

Response: EPA's computational toxicology research program is recognized nationally and internationally as bringing new science to bear on chemical safety and has made great progress in this area since the release of the NAS report.

19. Industry and federal research efforts have invested millions to better understand how chemicals interact with biological systems at human exposure levels in order to ensure development of human health risk assessment prediction models that are as accurate -and science-based as possible. However, IRIS has a long track record of dismissing these types of scientific biologically-based models and asserting that such approaches cannot prove the defaults are not warranted. Demanding that science proves a negative is an anti-scientific policy and indicates a deep seated prejudice against use of mode of action knowledge to replace defaults.

a. Why shouldn't EPA use the most up to date knowledge on mode of action and dose response at environmentally relevant exposures in lieu of outdated default approaches for hazard identification and dose response throughout the Agency, including in the IRIS Program?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that EPA's work reflects the best possible science.

b. Many scientists have criticized IRIS for its current framework and suggested using a weight of evidence framework. Thus, a litmus test for an improved IRIS will be adoption and use of a weight of evidence framework that incorporates all of the relevant and reliable data and knowledge of hypothesized modes of action, so that there is a clear and objective presentation of the extent to which existing data and knowledge do, or do not, support each hypothesis, including the default. Assuming you support such an approach, can you provide us with a timeline for when we might see such an approach adopted within IRIS?

Response: Hazard identification involves integrating evidence from human, animal, and mechanistic studies in order to draw conclusions about the hazards associated with exposure to a chemical. In general, IRIS assessments integrate evidence consistent with a framework developed by Sir Bradford Hill, which outlines aspects — such as consistency, strength, coherence, specificity, dose-response, temporality, and biological plausibility — for consideration of causality in epidemiologic investigations. These were later modified by others and extended to experimental studies. My understanding is that, currently, the National Center for Environmental Assessment uses existing guidelines that address these issues to inform assessments. If confirmed, I look forward to working with the National Center for Environmental Assessment on these issues.

20. In developing chemical assessments, such as those in IRIS, there is a blending of science, policy and science policy assumptions and choices throughout the evaluations.

a. Do you agree that IRIS assessments should explicitly acknowledge and transparently convey the science and assumptions around the science (i.e., handling uncertainty) inherent in IRIS assessments?

Response: Strong science and transparency are essential to the IRIS Program and important to all of EPA's work. If confirmed, I look forward to working with the National Center for Environmental Assessment on this issue.

21. In the 2009 NAS committee you chaired issued a report recommending there should be one unified approach for dose- response modeling. Unfortunately, such an approach may not always consider the millions of dollars of research that have been invested to explore the mechanisms of action of individual chemicals. Significant activities, coordinated by the Alliance for Risk Assessment, have been undertaken since 2009 to broaden the understanding of dose-response and to link different approaches to conducting dose response to problem formulation. This has resulting in more than 30 published case studies, illustrating qualitative categorization, quantitative screening and in-depth assessments.

a. Do you support linking dose response to problem formulation such that the complexity of the dose response approach is "fit for purpose" and reflects the range of decision options and likely regulatory impacts?

b. Do you believe that any approach implemented needs to put chemical specific information and test data ahead of standardize approaches?

c. Will you support an approach the puts chemical specific information and test data ahead of standardized approaches in the IRIS program?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that our work reflects the best possible science.

22. In the past you have suggested, in an NAS report you chaired, that information on nonchemical stressors should be incorporated into assessments and EPA should put further research dollars into evaluating the interactions between chemical and nonchemical stressors.

a. Considering the struggles ORD is having simply evaluating chemical stressors in the IRIS program, do you believe that ORD has the staff, with requisite qualifications and financial capacity, to also take on evaluations of nonchemical stressors?

b. Shouldn't ORD first convince Congress, NAS, and all other stakeholders that they can appropriately evaluate chemical stressors before broadening their scope?

Response: If confirmed, I look forward to further exploring this important issue with scientists within and outside of the agency.

23. As noted in "Science and Decisions: Advancing Risk Assessment" (NRC, 2009) "... formal consideration of numerous simultaneous chemical, physical, and psychosocial exposures with evaluation of background disease processes and other

dimensions of vulnerability could quickly become analytically intractable if the standard risk-assessment paradigm is followed, both because of the computational burden and because of the likelihood that important exposure and dose-response data will be missing. That points toward the need for simplification of risk- assessment tools in the spirit of iterative risk assessment..."

a. Since the NAS 2009 report there have been significant advances in the development and application of tiered, iterative tools for cumulative risk assessment, including development by the World Health Organization of a formal framework for risk assessment of combined exposure to multiple chemicals. Do you support use of this WHO framework? If not, why not?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

24. Currently the staff in the IRIS Program are the sole arbiters of determining whether and to what extent draft IRIS assessments should be revised to reflect input from peer reviewers and the public. EPA's own Scientific Advisory Board has recommended the use of a "monitor" or "editor."

a. Can you commit to ensuring that a 3rd party, independent of the IRIS Program, is tasked with ensuring that EPA staff have sufficiently considered and responded to peer reviewer and public input before assessments and other documents are finalized?

Response: Public comment and robust expert peer review is an important part of the agency's scientific work, and responding to public and peer review comments is an important step in completing a scientific product. It is my understanding that responses to public comments are documented in an appendix to each IRIS assessment so that interested parties can judge the adequacy of the response. If confirmed, I look forward to working with scientists in the agency to explore this issue further.

25. In previous comments on IRIS reform, you said that EPA's IRIS program is in "crisis" and is in need of reform while further stating "the sleeping giant is that EPA science is on the rocks ... if you fail, you become irrelevant, and that is kind of a crisis." Further, you admonished, "You can't fail at this time."

In response to a question you said, "We owe it to the American public, we owe it to the scientific community... to have risk assessments based in sound science. It would be better to do it right than destroy the credibility of the process."

The NAS report on formaldehyde was critical of the process as well as the underlying science that EPA used in its draft assessment. Your October 2011 testimony emphasized not only the importance of the process but, more importantly, the scientific conclusions or scientific content of the IRIS assessments.

a. Given the significance of this risk assessment to the scientific process and for restoring the public confidence in EPA's science, it is imperative that you commit to having the NAS retook at the next iteration of the formaldehyde IRIS assessment. Can I have your assurance that this peer review will take place?

Response: If confirmed, I will work to implement the recommendations of the NAS Formaldehyde Committee, not only for formaldehyde but for all IRIS documents. While I can assure there will be rigorous peer review of the revised formaldehyde document, I believe it is premature for me to provide assurance that another NAS committee will be convened specifically to re-review formaldehyde. I do look forward to working closely with the NAS to continually improve the quality of EPA science.

26. EPA, at the urging of stakeholders, will convene a scientific workshop on formaldehyde in the first half of 2014. Three key issues have been identified for discussion. I am concerned that this workshop will be similar to typical EPA science workshops of the past where the agency solicits input from a variety of stakeholders, irrespective of their qualifications, listens politely and without comment' and provides no resolution or feedback. Quite frankly, that is a waste of time and resources. I want to see difference in interpretation of the data, particularly from the epidemiological studies, narrowed. It is my hope that a robust dialog will help accomplish that. EPA staff should be engaged participants in the dialog, not mute listeners and I suggest EPA engage a professional facilitator and have the proceedings of the workshop published. Will you commit to be personally involved in the development and conduct of this workshop and ensure that the right scientists with the relevant subject matter expertise are at the table?

Response: Workshops to address important scientific issues, such as those related to assessing the health risks of formaldehyde, can help the agency in conducting its work. If confirmed, I look forward to working with the National Center for Environmental Assessment to ensure that this workshop is successful and includes experts with the appropriate background and knowledge.

27. The EPA workshop is timely, important at both the scientific and policy levels, and deals with scientific challenges of the highest order. How will you assure EPA integrates high quality information to help inform regulatory decisions for formaldehyde that presents complex challenges? How will EPA conduct a thorough, state-of-the-art WOE evaluation of the entire database?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

28. If you are confirmed, what commitment will you make to ensure EPA's scientific content and scientific conclusions are sound in light of the series of significant scientific shortcomings that the NAS Formaldehyde report identifies and the subsequent recommendations put forward?

Response: EPA has initiated a number of changes in response to the NAS Formaldehyde report. At the present time there is an NAS panel examining the overall IRIS process. If confirmed, I look forward to receiving the findings of the NAS and taking any necessary steps to address shortcomings and continually evaluate and improve the process.

29. As you know, Congress directed EPA to contract with the NAS to review the cancer and non- cancer IRIS assessments of inorganic arsenic. It is our understanding that a senior scientist in the IRIS program stated publically in a meeting that any recommendations from the NAS would be unlikely to change the agency's views on the arsenic IRIS assessment If confirmed, are you prepared to effect organizational and staffing changes to ensure that scientific integrity characterized by objectivity, transparency and scientific rigor is restored?

Response: I am not aware of any specific details relating to this purported statement by the senior scientist. As an active participant in NAS activities and Chair of multiple studies, I have tremendous respect for the work of the Academy. I can assure you that, if confirmed, I look forward to meeting with the NAS committee and working to implement recommendations they may provide to improve the IRIS assessment for both cancer and non-cancer effects of inorganic arsenic. I will also devote myself to ensuring integrity of all IRIS assessments and working with the staff to continually improve quality, objectivity, and transparency.

30. What are your views on how best to use systematic review as a tool to identify and review the body of scientific literature pertinent to a risk assessment of a chemical or substance? It is our understanding that the systematic review method developed by Dr. Birnbaum at the NTP and planned to be used by EPA IRIS automatically codes studies in the literature funded by industry as biased. That would mean that industry studies would not be given the same weight as other studies possibly funded by other organizations. How do you view this practice? How can you justify automatically ascribing bias to studies from or funded by industry, ignoring their scientific merit? Couldn't this distort the science by leaving out reliable and sound scientific studies?

Response: Systematic review of epidemiologic studies provides a valuable way to consider the findings from multiple investigations in evaluating the evidence for adverse effects. The review process also provides a framework for selection of studies for inclusion. The consideration of studies should be driven by the quality of the science. The systematic review process can address potential questions about investigator bias can still include studies that may be funded by industry. In risk assessment the systematic review process should be as robust as possible, with clear and transparent criteria for inclusion and exclusion of studies. Funding source alone should not be the basis for the decision to exclude a study from consideration. A full examination of study quality and potential bias is essential.

a. Others have pointed to different sources of bias, such as publication bias, which creates incentives, including increased likelihood of funding, toward studies that report positive associations; what are your views on this and similar concerns and how do you plan to take these kinds of bias into account?

Response: The issue of publication bias can be challenging. It is recognized that positive studies are more likely than negative studies to be published in peer reviewed journals. There may be many reasons contributing to this trend, including investigator choice not to submit negative studies and other design considerations that may contribute to the failure of a study to achieve statistically significant positive results. As a peer reviewer for many journals, I have never recommended rejection of a paper solely because of a negative result. Nor am I aware of any editors or editorial guidelines that recommend rejection of epidemiology studies with negative results. However, recognizing there may be a publication bias I believe it is very important that the systematic review process cast a broad net to be as inclusive as possible and include well conducted studies with both positive and negative findings.

31. The recent NAS interim report on inorganic arsenic states, "EPA proposes to use linear low-dose extrapolation as the default for cancer and non-cancer effects." This is in contrast with the EPA cancer guidelines, which supports the use of mode-of-action to determine the shape of the dose- effect relationship. It is also in contrast with general mechanistic understanding of non-cancer dose-response relationships. What are your views on linear versus non-linear approaches to risk assessment? Do you think EPA should pursue the establishment of a threshold at low exposures if the data support such association?

Response: Understanding the impact of chemical exposures at extremely low doses is perhaps the most challenging issue in risk assessment. Unfortunately, for the large majority of chemicals there is currently limited information about mode of action and great uncertainty about the dose-response relationship. For carcinogens, the default continues to be linear extrapolation at low doses. For non-carcinogens the dominant default has been to assume the existence of a threshold and use a safety factor approach in the face of limited information. The "Silver Book" provides guidance on addressing the issues of thresholds and urges that EPA develop tools to quantify non-cancer risks. Establishing a population threshold is very challenging, particularly when considering the most vulnerable members of our population such as developing infants or the elderly. If there is strong data supporting a threshold it should be presented as part of the risk assessment. In general, risk assessments should present the fullest characterization of risks possible, presenting both cancer and non-cancer findings, and providing risk managers with both linear and non-linear model results where there is sufficient data.

32. As an epidemiologist, please describe how you think the body of epidemiology on a specific substance should be reviewed. For instance, many observers, including the NAS, have criticized EPA for giving too much weight to epidemiological studies of large populations exposed to inorganic arsenic, such as the Taiwan data, just because of the large number of subjects, while giving little credence to studies from the US that observe smaller populations, although the lifestyles, including nutrition, of the large populations are totally different from US lifestyle. Meta-analysis studies have been conducted of US populations that address the smaller number of study subjects, but EPA has ignored those studies. These meta-analyses provide evidence that the dose-response relationship used by NRC 200 I from Taiwan is not consistent with findings from the US, and is higher than what would be derived from studies of US populations. What is your view on

the use of meta-analyses as a way to integrate information from smaller studies and to provide a reality check on EPA risk calculations?

Response: Within the field of epidemiology there is currently a great emphasis on improving the methods and application of meta-analysis and systematic review. This was in part stimulated by the recommendations of the NAS Formaldehyde report. The current process for review and refinement of the IRIS arsenic document will be addressing the challenge of improving the presentation and consideration of epidemiological findings. I am optimistic that an improved process will be more inclusive of smaller studies and provide a more transparent scientific basis for the selection of the critical studies used to calculate risks.

33. Studies from places like Bangladesh and Taiwan involve populations with very different nutritional statuses than is found in the US. The NAS Interim Report notes the importance of taking account of these differences in applying these study findings to the US (at p.59). How would you extrapolate from those studies to make the data relevant to the US?

Response: I agree that cultural, nutritional, and exposure difference should be considered in assessing and managing risks to the U.S. population. If confirmed a look forward to examining the recommendations of the NAS committee and actively working with the IRIS program to address the questions regarding relevance to the U.S. population.

34. How do you view the intersection between epidemiology and toxicology? Many critics believe EPA has been overly reliant on epidemiology and deemphasized mechanistic research that provides guidance for dose-response calculations. Some EPA critics suggest that a reluctance to identify modes of action is a deliberate approach by EPA to allow it to use epidemiological data to validate their modeling.

a. What steps can you take to correct this bias, whether real or perceived?

Response: Toxicology and epidemiology are both essential if we are to understand and manage risks. Both types of studies have advantages and limitations, and the best approach is to improve how we consider the full body of evidence from both of these disciplines. While well conducted studies of human populations are considered the "gold standard" for assessing human health risks, toxicology provides important information when human studies are lacking or not possible. The large majority of IRIS risk assessments are based upon animal toxicology, including assessments of cancer risk, because the dose response data from most human studies is very limited.

I do not believe there is a bias against toxicology studies. If confirmed, I will work with risk assessors and other scientists to provide clear criteria for consideration of epidemiology and toxicology in the risk characterization process. I will also support continued research to improve the application of mechanistic data to risk assessment.

b. Science commentators have noted a concern about "normative science," which is defined as "information that is developed, presented or interpreted based on an

assumed, usually unstated, preference for a particular policy choice." [Lackey, Robert T. Normative Science. *Terra Magazine,* Oregon State University, Volume 8, Issue 2 (2013).] What steps will you take to ensure that EPA's science assessments on your watch do not include this kind of normative science?

Response: I do not believe that "normative science" is practiced at EPA, and the best approach to this concern is open and credible peer review throughout the scientific process. It also it is important to separate the scientific assessment of evidence from the ultimate policy decision that must consider other social and economic factors.

c. Another type of concern has been identified: "EPA's use of assumptions that it claims are 'public health protective,' which err on the side of overstating risk when data are lacking.... Such inflated risk estimates can lead to overly stringent regulations and can scramble agency Priorities because the degree of precaution differs across chemicals. How do you intend to guard against this problem? What are your views on the use of empirical data as a "reality check" on overly conservative risk assessments, particularly those resulting from modeling or extrapolation of data? How do you view the application of additional safety factors - particularly when they become cumulative- for sensitive subpopulations or policy considerations such as environmental justice?

Response: First, I believe that the fundamental mission of EPA is to protect public health, and therefore agree with approaches that are "public health protective". I also believe that the fundamental challenge in assessing chemical risks is a lack of data. Therefore, it is not really valid to say that the EPA assumptions "overstate the risks when data are lacking". For example, in the absence of data about a specific unrecognized health effect it may be the case that risks are underestimated. The current drinking water emergency in West Virginia is an example of the challenge of safeguarding public health when the data about health effects is limited. In the absence of data, safety factors provide a time tested public health strategy to safeguard communities.

I agree that more specific evidenced based approaches to safety factors and the protection of vulnerable subpopulations are needed. Also, risk characterization should include presentation of multiple modeling approaches to assist decision making and provide a "reality check" based on empirical data. Cumulative risk presents a difficult challenge. I support continued research to refine our methods of considering interaction of multiple stressors in risk assessment, particularly regarding sensitive populations and environmental health disparities.

35. The NAS 2008 Report: <u>Science and Decisions: Advancing Risk Assessment,</u> frequently referred to as the "Silver Book" strongly recommended that EPA should consider the regulatory impacts of its IRIS hazard assessments. Since then, EPA has proposed IRIS assessments, including the cancer assessment for inorganic arsenic, which would drive regulatory standards below naturally occurring background levels in soil and water. EPA national and regional managers were highly critical of the IRIS proposed 17x increase in the cancer slope for inorganic arsenic, saying the science was " detached from reality" and would have "disastrous consequences" for EPA programs including Safe Drinking Water and RCRA.

The NAS Silver Book urges EPA to perform extensive examination of risk management implications and options in the first phase of human health hazard assessments. It further recommends involving EPA national program managers (Air, Water, CERCLA, RCRA) in this early phase of assessment so that EPA can then use risk assessment to make more informed choices among those options.

Do you support this particular recommendation from the NAS Silver Book? Do you believe EPA's IRIS assessments must properly consider the "real world" regulatory and risk management implications of its hazard assessments?

Response: As Chair of the NAS Committee, I strongly support the recommendations of the "Silver Book". It is important that risk assessment be designed to address the needs of decision makers and risk managers. However, the risk management process should be recognized as distinct from the characterization of health risks. The ultimate decision on the application of risk information for risk management is a policy decision. Issues of feasibility and cost are essential components of the decision process and are not driven by dose response findings. The risk management decision must consider the "real world". The full process presented in the Silver Book is a continuum from problem formulation through risk management.

36. What is the cost of EPA's Hydraulic Fracturing study on the potential impacts of hydraulic fracturing on drinking water resources thus far? How long has the agency been engaged in the study? What has the agency done in terms of testing?

Response: To my knowledge, the work began in 2010 in response to a request from Congress. If confirmed, I will look into the budget of the EPA's study as well as the specific research projects.

37. Has the EPA done any testing in real time for sites that are being drilled now? My understanding is that the agency has tested several sites that were drilled years ago, which is a problem because EPA does not have a good baseline of information and there are other factors which could have caused contamination (agriculture, mining, etc.). How does EPA plan on overcoming the lack of good baseline information and ensuring no conclusions are drawn about hydraulic fracturing without first ruling out any other possible sources of contamination?

Response: Although I participated in a 2011 EPA SAB review of the study, I am not familiar with the specific details of EPA's sampling work, the availability of baseline information, or how the agency will use this information to draw conclusions about potential sources of contamination. If confirmed, I look forward to working with scientists in the agency to explore this issue further.

38. Has the agency has expanded the scope of the study beyond looking at groundwater? What is the full scope of what the agency is now studying? What are all the various pieces that will be included in the study? Were those asked for by Congress? If the study has been expanded, what justification does the agency have for doing so?

Response: I am not familiar with the specific details of the study including the scope, as it may have changed from the Study Plan that I commented on in 2011. If confirmed, I will support a scope that is responsive to Congress' request.

39. What has been the extent of EPA's work with DOE and USGS to date on the study?

Response: If confirmed, I look forward to gaining an understanding of how EPA has worked with other agencies to ensure that research efforts are done efficiently and effectively. However, at this time I do not know the extent to which EPA is working with other federal agencies on the hydraulic fracturing study.

40. How are you accounting for fracturing technology, as it is changing quickly and beneficially, as part of the study?

Response: I am not familiar with EPA's approach for staying up to date on changes in industrial practices related to hydraulic fracturing. If confirmed, I look forward to working with scientists in the agency to ensure that this study is based on the best available science.

41. There has been some controversy over methane leakage from shale development and hydraulic fracturing. But a recent study from the University of Texas that was published in the Proceedings of the National Academy of Sciences found that methane leaks from natural gas development were in line with EPA's data, which showed a leakage rate of only about 1.5 percent. There are several other studies, some of which found high leakage rates, but most seem to suggest that leakage is low and manageable. Based on your review of the scientific literature, what's your understanding of methane leakage from natural gas development, and do you see any environmental benefits of increasing natural gas production and use in the United States?

Response: I have not reviewed the National Academy of Sciences paper and cannot speak to the issue of methane leakage at this time. If confirmed, I will look into this issue.

42. Former EPA administrator Lisa Jackson said, 'I'm not aware of any proven case where the fracking process itself has affected water.' Secretary of Energy Ernest Moniz has said 'I still have not seen any evidence of fracking per se contaminating groundwater.' Interior Secretary Sally Jewell said she is 'not aware of documented cases' of hydraulic fracturing contaminating groundwater. I realize the EPA is currently studying this issue, but based on the evidence already available, do you agree with these officials' assessments?"

Response: I am not familiar with the details of the scientific literature, but will look into the issue if I am confirmed.

43. The increase in domestic energy production is due to the application of two proven engineering technologies- hydraulic fracturing and horizontal drilling. Hydraulic

fracturing has been used commercially since the 1940s and directional drilling has been around since the 1930s. Development of resources using these technologies is responsible for 2.1 million American jobs and this number is expected to rise to 3.9 million in 2025. Furthermore, tens of thousands of wells are drilled every year using the process, and we have seen over a million wells drilled in the US with no cases of groundwater contamination. Do you agree that hydraulic fracturing is critical to our economy and our national security? Do you agree that it is a proven technology that has been used safely for over half a century and can be used safely?

a. Are you aware of any cases where hydraulic fracturing has contaminated drinking water?

Response: Energy production is critical to our economy and our national security and hydraulic fracturing should be done in a manner that protects human health and the environment. At this time, I cannot speak to the level of safety associated with hydraulic fracturing, as it has not been my professional focus to date. However, if confirmed, I am committed to ensuring that EPA has all of the information available about the safety of the technology. As I mentioned during my hearing last month, from my own experience, having done many studies of groundwater contamination, I am not familiar with a specific case of drinking water contamination from hydraulic fracturing.

44. As part of the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water, the conference report stated that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

a. Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study? Do you believe it is the SAB ad hoc panel's role to peer review all of the study's reports and projects as part of the study?

Response: I believe that rigorous peer review is an important element to ensure the quality of the science. I am not familiar with the details of ORD's peer review plan for the study. If confirmed, I will look into this issue and support decisions that ensure valid and accurate data as well as transparency.

45. Also included in the conference report is the statement that "The Agency shall consult with other Federal agencies as well as appropriate State and Interstate regulatory agencies in carrying out the study..."

a. Are you aware of any other federal agencies currently being consulted in the study? Which agencies will you consult with should you be confirmed and head the ORD and lead the study?

Response: I am not familiar with the extent to which EPA is working with other federal agencies. If confirmed, I look forward to learning about how EPA has worked with other agencies to ensure that research efforts are done efficiently and effectively.

46. Recently, EPA Administrator Gina McCarthy was quoted as saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifers."

a. Do you agree with that statement?

Response: I am not familiar with the Administrator's statement. If confirmed, I will look forward to learning more about the issue.

47. This June, ORD announced it would abandon its flawed drinking water investigation in Pavillion, WY and would instead support a further investigation by the State of Wyoming.

a. Given the flawed science on display by the agency in Pavillion and ORD's withdrawal, will you exclude the agency's work and data prior to June 2013 from the agency's Congressionally-requested study on the relationship between hydraulic fracturing and drinking water? If not, why not?

Response: I am not familiar with the specific details of ORD's support of the Agency's Pavillion investigation. If confirmed, I look forward to learning about EPA's work in this area.

b. ORD abandoned its investigation, yet according to agency statements, continues to "stand behind its work and data." How can the agency reconcile these directly contradictory actions? How would you explain to the American people that continuing a flawed investigation is not worth taxpayer resources, yet the agency "stands behind" the work and data that it abandoned? If confirmed, will you correct the record and explain to the public that EPA does not stand behind flawed science?

Response: I am not familiar with the specific details of the agency's Pavillion investigation. If confirmed, I will look into this issue.

c. Are you aware of criticisms of EPA's work in Pavillion by other federal agencies? How would you respond to those criticisms?

Response: I am not aware of any specific criticisms from any agency.

d. How are ORD and the EPA regional office in Denver currently supporting the State of Wyoming's investigation?

Response: I am not aware of any specific details of the investigation.

48. Is there a reason, particularly as it relates to air science impacts (PM, ozone, etc.) that we don't see the agency using nonlinear threshold analysis? There are concerns that EPA's analysis is allowing the agency to count benefits that just don't exist, or otherwise set standards below naturally occurring background levels. We've seen this in chemical assessments as well, such as on dioxin and inorganic arsenic. How do we resolve the distance between theoretical benefits and empirical evidence?

Response: EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that all of our work reflects the best possible science.

49. One of the most important responsibilities of the EPA Office of Research and Development is the development of health assessments for EPA's IRIS program. In September 2011, EPA issued its long-awaited "Toxicological Review of Trichloroethylene (CAS No. 79-01-6) in Support of Summary Information on the Integrated Risk Information System (IRIS)."

The IRIS Assessment contains a reference concentration ("RfC") of 0.0004 ppm (0.4 ppb or 2 J.Lg/m3) and a reference dose ("RfD") of 0.0005 mglkg/day for trichloroethylene (TCE). These are values that are considered by EPA to be protective for all noncancer critical effects. EPA's derivation of the RfC/RfD for TCE is based, in part, on Johnson *eta/.*, Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environmental Health Perspectives 111: 289-92 (March 2003).

The RfC/RfD is within the range of background concentrations of TCE in urban air. There is a significant ongoing dispute among the EPA regions as to whether and how this RfC/RfD derived from Johnson *et al* .should be the basis for a short-term TCE exposure limit at Superfund sites. Thus, the proper interpretation and use of this non-GLP study in risk assessment is a question of the highest priority to EPA's Superfund program.

As noted in the peer review of a recent EPA "TSCA Chemicals Work Plan" assessment of TCE which was highly critical of EPA's reliance on Johnson *et al/.*, "[o]ne of the fundamental tenants in science is the reliability and reproducibility of results of scientific investigations."

The peer reviewers noted:

- **At least two GLP-compliant studies conducted under both EPA and OECD guidelines have been unable to reproduce the effect seen by Johnson *et al.*, despite the participation in one of the studies by Johnson herself.**

- **The dose-response relationship reported in Johnson *et al.* for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.**

- **The congenital heart defect incidence in control animals in Johnson *et al.* was 86 times the historical control incidence in Charles River rats.**

- **As California EPA noted in declining to rely upon Johnson *et* al, "These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits. The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al.,2004)."**

Is EPA concerned that the TCE IRIS Assessment appears to rely on an irreproducible study result? Is there any effort underway to correct this Assessment? Does this information presented seem to indicate that the EPA's IRIS program is no longer "crisis" and is being based on the best available science?

Response: I am not aware of any EPA effort to review the IRIS assessment for TCE. EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will work with scientists within and outside of the agency to ensure that our work reflects the best possible science.

Senator James Inhofe

1. Dr. Burke, as head of the EPA's R&D Office, you are going to have responsibility for the Congressionally-requested study on the relationship between hydraulic fracturing and drinking water. The conference report mandating the study state that "the study [shall] be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data." The EPA Science Advisory Board (SAB) has set up an ad hoc panel specifically to provide the peer review for the study and its components.

Will the SAB ad hoc panel peer review all of the reports and projects that are developed as part of the study?

Response: I am not familiar with the details of ORD's peer review plan for the study. If confirmed, I will look into this issue and support decisions that ensure valid and accurate data as well as transparency.

2. Dr. Burke, a few weeks ago the EPA Administrator was quoted saying that "developing some kind of uniform standard [as it relates to water] is very difficult given different geologies and different uses of water, different aquifiers."

Do you agree with this statement?

Response: I am not familiar with the Administrator's statement. If confirmed, I will look forward to learning more about the issue.

3. Dr. Burke, you have served as a member of EPA's Science Advisory Board. The SAB serves an important function especially in regard to providing advice on EPA's study on hydraulic fracturing and drinking water.

a. In your capacity on the SAB, did you have an opportunity to review EPA's study plan?

Response: As a member of the Charter Board of the Science Advisory Board, I did review the study plan. I submitted written comments on July 5, 2011. These comments are part of the public record and are available on the SAB website. The comments were generally supportive of the study plan and included suggestions for reaching out to local health officials and improving the evaluation of potential health risks to communities.

b. Do you agree that all of the individual components of the study should be deemed highly influential scientific assessments?

Response: I am not familiar with the EPA practices regarding defining a study as a highly influential scientific assessment. If confirmed I look forward to working with the scientific staff and learning more about these designations and their impact on the peer review process.